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6 PRESCRIPTION DRUG COVERAGE IN THE MEDICARE

7 PROGRAM

8 TUESDAY, APRIL 30, 2019

9 House of Representatives

10 Subcommittee on Health

11 Committee on Energy and Commerce

12 Washington, D.C.

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16 The subcommittee met, pursuant to call, at 10:30 a.m.,

17 in Room 2322 Rayburn House Office Building, Hon. Anna G.

18 Eshoo [chairwoman of the subcommittee] presiding.

19 Members present: Representatives Eshoo, Engel,

20 Butterfield, Matsui, Castor, Sarbanes, Lujan, Schrader,

21 Kennedy, Cardenas, Welch, Ruiz, Dingell, Kuster, Kelly,

22 Barragan, Blunt Rochester, Rush, Pallone (ex officio),

23 Burgess, Upton, Shimkus, Guthrie, Griffith, Bilirakis, Long,

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24 Bucshon, Brooks, Mullin, Hudson, Carter, Gianforte, and
25 Walden (ex officio).

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28 Staff present: Mohammad Aslami, Counsel; Kevin Barstow,
29 Chief Oversight Counsel; Billy Benjamin, Systems
30 Administrator; Jacquelyn Bolen, Professional Staff; Jesseca
31 Boyer, Professional Staff Member; AJ Brown, Counsel; Jeff
32 Carroll, Staff Director; Jacqueline Cohen, Chief Environment
33 Counsel; Sharon Davis, Chief Clerk; Luis Domingues, Health
34 Fellow; Jennifer Epperson, FCC Detailee; Elizabeth Ertel,
35 Office Manager; Adam Fischer, Policy Analyst; Jean Fruci,
36 Energy and Environment Policy Advisor; Evan Gilbert, Press
37 Assistant; Lisa Goldman, Counsel; Waverly Gordon, Deputy
38 Chief Counsel; Tiffany Guarascio, Deputy Staff Director;
39 Caitlin Haberman, Professional Staff Member; Alex Hoehn-
40 Saric, Chief Counsel, C&T; Megan Howard, FDA Detailee; Zach
41 Kahan, Outreach and Member Service Coordinator; Rick Kessler,
42 Senior Advisor and Staff Director, Energy and Environment;
43 Saha Khaterzai, Professional Staff Member; Chris Knauer,
44 Oversight Staff Director; Brendan Larkin, Policy Coordinator;
45 Una Lee, Senior Health Counsel; Jerry Leverich, Counsel;
46 Jourdan Lewis, Policy Analyst; Perry Lusk, GAO Detailee;

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47 Dustin Maghamfar, Air and Climate Counsel; John Marshall,
48 Policy Coordinator; Kevin McAloon, Professional Staff Member;
49 Dan Miller, Policy Analyst; Jon Monger, Counsel; Elysa
50 Montfort, Press Secretary; Phil Murphy, Policy Coordinator;
51 Lisa Olson, FERC Detailee; Joe Orlando, Staff Assistant;
52 Kaitlyn Peel, Digital Director; Mel Peffers, Environment
53 Fellow; Alivia Roberts, Press Assistant; Tim Robinson, Chief
54 Counsel; Chloe Rodriguez, Policy Analyst; Nikki Roy, Policy
55 Coordinator; Samantha Satchell, Professional Staff Member;
56 Andrew Souvall, Director of Communications, Outreach and
57 Member Services; Sydney Terry, Policy Coordinator; Kimberlee
58 Trzeciak, Senior Health Policy Advisor; Rick Van Buren,
59 Health Counsel; Eddie Walker, Technology Director; Teresa
60 Williams, Energy Fellow; Tuley Wright, Energy and Environment
61 Policy Advisor; C.J. Young, Press Secretary; Jennifer
62 Barblan, Minority Chief Counsel, O&I; Mike Bloomquist,
63 Minority Staff Director; Adam Buckalew, Minority Director of
64 Coalitions and Deputy Chief Counsel, Health; Robin Colwell,
65 Minority Chief Counsel, C&T; Jerry Couri, Minority Deputy
66 Chief Counsel, Environment & Climate Change; Jordan Davis,
67 Minority Senior Advisor; Kristine Fargotstein, Minority
68 Detailee, C&T; Margaret Tucker Fogarty, Minority Staff
69 Assistant; Melissa Froelich, Minority Chief Counsel, CPAC;

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70 Theresa Gambo, Minority Human Resources/Office Administrator;
71 Caleb Graff, Minority Professional Staff Member, Health;
72 Brittany Havens, Minority Professional Staff, O&I; Peter
73 Kielty, Minority General Counsel; Bijan Koochmaraie, Minority
74 Counsel, CPAC; Tim Kurth, Minority Deputy Chief Counsel, C&T;
75 Ryan Long, Minority Deputy Staff Director; Mary Martin,
76 Minority Chief Counsel, Energy & Environment & Climate
77 Change; Sarah Matthews, Minority Press Secretary; Brandon
78 Mooney, Minority Deputy Chief Counsel, Energy; James
79 Paluskiewicz, Minority Chief Counsel, Health; Brannon Rains,
80 Minority Staff Assistant; Zach Roday, Minority Communications
81 Director; Kristen Shatynski, Minority Professional Staff
82 Member, Health; Alan Slobodin, Minority Chief Investigative
83 Counsel, O&I; Peter Spencer, Minority Senior Professional
84 Staff Member, Environment & Climate Change; Natalie Sohn,
85 Minority Counsel, O&I; Danielle Steele, Minority Counsel,
86 Health; Everett Winnick, Minority Director of Information
87 Technology; and Greg Zerzan, Minority Counsel, CPAC.

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88 Ms. Eshoo. The Subcommittee on Health will now come to
89 order. Good morning, everyone. And I am going to recognize
90 myself for five minutes for an opening statement.

91 Our subcommittee continues its work to lower drug prices
92 for seniors and for families across our country. Last month
93 the members of the subcommittee passed six bipartisan bills
94 to make prescription drugs more affordable by increasing
95 market competition. Today, we are going to take a close look
96 at the Medicare program to understand what is leading to high
97 prescription drug costs for the 60 million Americans who get
98 their drugs through Medicare.

99 To inform our work, we have present to hand, Dr.
100 Matthews, the Executive Director of MedPAC, the Medicare
101 Payment Advisory Commission. MedPAC provides valuable
102 nonpartisan advice to Congress on the Medicare program.

103 We need expert advice. Drug prices are skyrocketing and
104 Congress must act, and wants to act. Before we do, we have
105 to, I believe, do as best we can to do a deep dive to
106 understand the Medicare program and its challenges.

107 Medicare accounts for one out of every three dollars
108 spent on prescription drugs. And drug spending is growing
109 rapidly each year. Whether a patient gets their drugs at the
110 hospital under the Part B program, or the pharmacy counter

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111 through the Part D program, costs are rising.

112 In the Part B program, Medicare drug spending doubled
113 from 2009 to 2017. We spent \$32 billion, that's with a B, on
114 Part B drugs in 2017. Part D drug spending has also nearly
115 doubled over the past ten years. We spent \$80 billion in the
116 Part D program in 2017.

117 These rising costs are putting, I believe, unsustainable
118 pressure on the Medicare program and on America's families.
119 In a recent Kaiser Family Foundation poll, 23 percent of
120 seniors say it is difficult to afford their medications. I
121 know it is true for my constituents, and for all of my
122 colleagues constituents as well.

123 We hear from people on a consistent basis. They are
124 worried that when they leave their doctors' office
125 appointments with a new prescription written out for them
126 they are not sure whether they can pay for it, afford it or
127 not.

128 America leads the world in innovative health care, but
129 soon, few people will be able to afford this cutting-edge
130 care. This committee, through our work on the 21st Century
131 Cures Act, promoted development of novel, breakthrough
132 treatments. But, with the development of these treatments
133 has come increased spending.

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134 Spending on drugs in specialty tiers has grown nearly
135 1,000 percent over ten years, from \$3.4 billion in 2007 to
136 \$37.1 billion in 2017.

137 Because Medicare has no limit on out-of-pocket spending,
138 people who rely on specialty drugs are hit especially hard.
139 One study found needing a single specialty drug could cause
140 people on Medicare to spend anywhere from \$2,000 to \$16,000
141 out-of-pocket annually.

142 Every senior deserves high-value, innovative medicine to
143 improve their lives, but rapidly increasing costs affect
144 their ability to get the drugs they need. So, we need
145 solutions.

146 Today's hearing is yet another step closer to our, well,
147 I would say it is a very important step towards our bringing
148 forward solutions to what I just described.

149 So, welcome to Dr. Matthews. And I look forward to your
150 expert advice on improving the Medicare Part D program.

151 And with that, I will now recognize Mr. Bucshon, who
152 will -- is taking the place of Dr. Burgess this morning, who
153 has to be at the Rules Committee.

154 Welcome. And it is nice to sit next to you. Mr.
155 Bucshon. Thank you. It is nice to sit next to you, also.

156 Madam Chairwoman, thank you for holding this important

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157 hearing today. I appreciate this opportunity to members to
158 take a deeper look at the drug coverage offered to seniors
159 under Medicare Part B and Part D. These programs provide
160 critical health care coverage for American seniors. And
161 getting a better understanding of where these programs are
162 today will help ensure that we can -- they can meet the needs
163 of seniors tomorrow.

164 As we have been exploring drug pricing in this
165 subcommittee and in the committee, this is an important
166 opportunity to hear from the Medicare Payment Advisory
167 Commission, a nonpartisan organization that is tasked with
168 providing technical advice to Congress. MedPAC is an
169 important resource for Congress as we look to address
170 challenging issues, such as Medicare's ability to provide
171 adequate and affordable drug coverage to seniors, and the
172 impacts any programmatic changes may have on beneficiaries,
173 providers, and taxpayers.

174 Medicare Part B covers drugs that are administered by a
175 physician through infusion or injection in an office or
176 outpatient setting. These drugs include many high-cost
177 chemotherapy agents, and other critical lifesaving
178 medications.

179 Medicare Part D provides a prescription drug benefit to

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180 beneficiaries, and participation is voluntary. The Part D
181 program has been a success. According to a recent MedPAC
182 report, it has improved beneficiaries' access to prescription
183 drugs.

184 Generic drugs now account for nearly 90 percent of the
185 prescriptions filled. Enrollees' average premiums for basic
186 benefits have remained around \$30 per month for many years.
187 More than eight in ten Part D enrollees report they are
188 satisfied with the program. Furthermore, because of the
189 deliberate structure of Part D, which incentivizes private
190 health insurers to compete against one another, the program
191 has been wildly successful in holding down costs to
192 taxpayers.

193 In 2016, Part D expenditures were approximately \$100
194 billion, which was less than half of the \$205.5 billion
195 projected by the CBO in 2006. In fact, over the first ten
196 years that Part D was in operation, CBO data shows that the
197 program cost taxpayers \$555.8 billion less than originally
198 projected.

199 While Part B and Part D operate differently and cover
200 different medications, they both provide seniors with access
201 to necessary treatments and lifesaving drugs. It is
202 important that any suggested changes to these program be well

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203 understood, and the impacts on patients, providers, and
204 taxpayers be carefully considered.

205 The Trump administration has made a vow to lower costs
206 of drugs, and has proposed changes to both Medicare Part D, B
207 and D, to address the rising list prices, out-of-pocket costs
208 for patients, and costs to the Federal Government. These
209 proposed changes to how Medicare operates and provides drugs
210 under Part B and D should be carefully analyzed to understand
211 their full impact.

212 It is important that members of Congress on both sides
213 of the aisle work together and, with the Administration, find
214 solutions to lower list prices and out-of-pocket costs while
215 maintaining robust access to seniors, without penalizing
216 physicians, taxpayers, or stifling innovation.

217 As the Energy and Commerce Committee considers
218 legislative proposals to address the high cost of drugs, I
219 appreciate the important resource that MedPAC provides
220 Congress. I want to thank our witness Dr. Matthews for being
221 here today and I look forward to your testimony.

222 I yield back.

223 [The statement of Mr. Bucshon follows:]

224

225 ***** COMMITTEE INSERT *****

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246 Ms. Eshoo. I thank the gentleman for his statement.

247 The chair now recognizes Mr. Pallone, chairman of the full

248 committee, for five minutes for his opening statement.

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249 The Chairman. Thank you, Madam Chair.

250 Today we are continuing this committee's important work
251 in providing Americans relief when it comes to the
252 skyrocketing price of prescription drugs. We have already
253 passed several bills that will remove barriers that delay
254 cheaper generic drugs from coming to market. And today we
255 are focusing on the rising costs of prescription drugs in the
256 Medicare program so we can begin to think about solutions to
257 drive down costs for America's seniors and for the Federal
258 Government.

259 We have all heard the stories about Americans who cannot
260 afford their medications, who are rationing their life-saving
261 therapies, or choosing not to fill their prescriptions
262 because they instead need to put food on the table. And, at
263 the same time, we have watched as prescription drug spending
264 continues to cost the Federal Government more and more each
265 year. And we simply can't afford to wait any longer to fix
266 this broken system.

267 The way drug prices are set, and the opaque drug supply
268 chain, has fostered a system that can be gamed for profit at
269 the expense of seniors who need access to affordable
270 medicines.

271 I want to thank James Matthews, the Executive Director

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272 of MedPAC, for testifying. MedPAC is a critical resources to
273 Congress and provides invaluable nonpartisan policy
274 recommendations on how to improve the Medicare program for
275 beneficiaries. And MedPAC has conducted significant work on
276 prescription drug pricing in the Medicare program. And I
277 look forward to hearing from Dr. Matthews on how we pay for
278 drugs under Parts B and Prescription drugs, and how we can
279 lower drug costs.

280 But this is particularly concerning in the Part D
281 program, where high cost specialty drugs represent a large
282 and growing share of the Part D spending. According to
283 MedPAC, spending for specialty drugs has grown more than ten
284 times since the beginning of the Part D program. And that
285 growth resulted in specialty drug claims making up nearly a
286 quarter of all gross Part D spending in 2017. And it is now
287 estimated that between 2019 and '23, nearly two-thirds of
288 newly-launched drugs will be considered specialty drugs.

289 These high cost specialty drugs are partly responsible
290 for the fact that each year more beneficiaries are reaching
291 the catastrophic phase of the Part D benefit. In 2016, over
292 360,000 Medicare beneficiaries reached the catastrophic limit
293 of \$4,850 out-of-pocket, that threshold, in just one visit to
294 the pharmacy. That's a significant jump from only 33,000

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295 beneficiaries in 2010. And this leaves beneficiaries,
296 particularly those with serious, chronic, or life-threatening
297 diseases at risk for substantial out-of-pocket costs.

298 So, I look forward to hearing from Dr. Matthews about
299 MedPAC's proposal to add an out-of-pocket limit to the Part D
300 program. I hope we can work together on a bipartisan basis
301 to implement some of these ideas in order to provide seniors
302 with peace of mind that they will be protected if they need
303 these high-cost therapies.

304 MedPAC has also noted that the current structure of the
305 Part D program may be eroding incentives for Prescription
306 Drug Plans to control costs. Currently, the Federal
307 Government pays 80 percent of the costs for Part D benefits
308 in the catastrophic phase of coverage. And this means that
309 payers may not be incentivized to effectively manage costs
310 for their most expensive enrollees since the government is
311 footing most of the bill.

312 We will also discuss Part B drug spending, which has
313 increased at an average rate of almost 10 percent annually
314 for the past decade. These increases are primarily driven by
315 rising drug prices, which have a direct impact on out-of-
316 pocket costs for beneficiaries, because most beneficiaries
317 are responsible for paying a 20 percent coinsurance on their

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318 Part D drug -- Part B drugs. And so, I look forward to
319 examining proposals to slow rapid price growth and increase
320 competition in the Part B drug program as well.

321 And while most groundbreaking drugs are coming to
322 market, and they really are saving lives, and increasing
323 quality of life, and helping seniors to better manage
324 diseases, but these therapies often come with price tags that
325 are unaffordable for the average American. And these prices
326 represent a significant long-term financial challenge to the
327 Federal Government and to the Medicare program. So, we have
328 to find solutions that promote greater affordability and
329 access. And I look forward to that discussion today.

330 So, I don't think anybody else wants my time, Madam
331 Chair, I yield back. Thank you. Ms. Eshoo. The gentleman
332 yields back.

333 The chair now is pleased to recognize Mr. Walden, the
334 ranking member of the full committee, for five minutes for
335 his opening statement.

336 Mr. Walden. Thank you, Madam Chairman. And thank you
337 for holding this hearing.

338 This hearing continues this committee's important work
339 on bringing down the costs of prescription drugs for seniors,
340 frankly for all Americans, and patients across the country,

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341 but especially seniors in the Medicare program.

342 I want to thank our witness. Doctor, we are delighted
343 to have you here as Executive Director of Medicare's Payment
344 Advisory Commission, more commonly known as MedPAC. The work
345 you do there, and your team, is really important. MedPAC
346 provides a really valuable service to lawmakers. And as an
347 independent nonpartisan commission, provides data analysis
348 and policy recommendations to improve the Medicare system,
349 which we all care deeply about.

350 We value this input and we really appreciate the work of
351 the commission.

352 Today we call on MedPAC's expertise with respect to
353 rising prescription drug costs in the Medicare system. This
354 committee has a long history on this issue, including the
355 creation of Part D, which some of us were on the committee
356 then and did the full overnight mark-up, and 60 amendments,
357 and a lot of back and forth, but we got it done. That was
358 back in 2003.

359 Nearly 44 million Medicare beneficiaries use Medicare
360 Part D today. I remember there was talk then that nobody
361 would write one of those plans, it will never get off the
362 ground, it will cost a fortune. And, actually, it has worked
363 pretty well. Now there are some tweaks all these years later

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364 we need to look at.

365 It is important to note the overwhelming majority of
366 seniors who have Part D are satisfied with their plan. The
367 premiums have remained stable and, frankly, relatively low
368 throughout the program's history. The program has largely
369 been a good success. And harnessing the power of competition
370 to create a working market has given consumers more choices
371 than anybody thought possible, and has helped keep prices
372 down.

373 Now, there are challenges to Medicare Part D that have
374 grown over time and have saddled some beneficiaries with
375 significant increases in their out-of-pocket costs.
376 Additionally, the share of Medicare Part D spending
377 attributable to the catastrophic stage of coverage, has
378 increased from 14 percent of the program costs in 2006 to 40,
379 four zero, percent in 2017. So, we should confront these
380 issues now to modernize Part D and keep drugs affordable for
381 seniors, and address misaligned incentives to drive up costs.

382 The same goes for Part B where a small number of drugs
383 represent a large percentage of government and beneficiary
384 spending on the program. As others have noted, Part B drug
385 spending has increased almost 10 percent per year since 2009.
386 While there has been tremendous development, especially

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387 drugs, that can effectively treat cancer and other diseases
388 in amazing ways, these rising costs must also be confronted.

389 So, I look forward to hearing from our witnesses, or our
390 witness, on whether the current structure of how Part B drugs
391 are reimbursed can and should be modified to foster
392 competition and to lower prices. One consistent concern I
393 hear about from my constituents in Oregon, and I have done 20
394 town halls so far this year, is the high cost of prescription
395 drugs. I know that my colleagues on both sides of the aisle
396 have heard similar concerns in their districts as well.

397 We have worked in a bipartisan manner on lowering drug
398 costs over the last several years. During my tenure as
399 chairman of this committee and during the first few months of
400 this year we have continued those efforts. So, I believe
401 that that should continue. And this hearing will help us
402 further our bipartisan work to lower drug costs for American
403 consumers and seniors who rely upon Medicare.

404 So, thanks again, Doctor, for being here today and the
405 good work you do at MedPAC.

406 With that, Madam Chair, I yield back. Ms. Eshoo. The
407 gentleman yields back.

408 The chair would like to remind members that, pursuant to
409 committee rules, all members' written opening statements

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410 shall be made part of the record. So, get them in.

411 I would now like to introduce our witness for today's
412 hearing, Dr. Jim Matthews. He serves as the Executive
413 Director of the Medicare Payment Advisory Committee, and a
414 very important position, a very important commission. And
415 once again, thank you for being here today to be instructive
416 to us. And we certainly look forward to your testimony.

417 You have testified many times in Congress, so I don't
418 think I need to explain the lighting system to you. The most
419 important one is when it turns red, because that is when your
420 five minutes are up.

421 So, Dr. Matthews, thank you again. You are now
422 recognized for five minutes of testimony.

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423 STATEMENT OF JAMES E. MATTHEWS, PH.D., EXECUTIVE DIRECTOR,
424 MEDICARE PAYMENT ADVISORY COMMISSION

425

426 Mr. Matthews. Thank you. Good morning, Chairwoman
427 Eshoo, Dr. Bucshon, and distinguished committee members. On
428 behalf of MedPAC, a nonpartisan, independent congressional
429 advisory agency, I am here to convey information on
430 Medicare's payments for prescription drugs.

431 First, I will describe how Medicare pays for drugs under
432 Part B, and discuss recent trends in spending and
433 utilization.

434 Second, I will do the same with Part D.

435 Lastly, I will touch briefly on commission
436 recommendations that address these trends.

437 I will start with Part B. Part B covers drugs that are
438 typically administered by a provider, such as infused
439 chemotherapy drugs. Medicare pays for Part B drugs based on
440 the average sales price that manufacturers report for a drug,
441 net of most rebates and discounts. Medicare pays providers
442 the actual sales price, plus a 6 percent add-on, regardless
443 of how much the individual provider has spent to purchase the
444 drug. Medicare makes a separate payment to the provider for
445 administering the drug.

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446 Part B spending has grown roughly 10 percent a year
447 since 2009, reaching \$32 billion in 2017. Growth in Medicare
448 spending for drugs under Part B is driven largely by rising
449 prices, which account for two-thirds of overall spending
450 growth, and which reflect manufacturers' significant pricing
451 leverage. Under the current payment system, as drug prices
452 rise, Medicare's payments will follow. And Medicare has few
453 tools to affect prices under Part B.

454 Part D uses private plans to deliver Medicare's
455 outpatient prescription drug benefit. Part D plans negotiate
456 with pharmacies over payment rates for filling prescriptions,
457 and with drug manufacturers for post-sale rebates. Medicare
458 is prohibited from interfering in these negotiations.

459 There are two components of Medicare's payments to plans
460 for Part D basic benefits.

461 First, there is a per-enrollee payment based on plans'
462 bids, which reflects their expected costs for the Part D
463 benefit for an average enrollee.

464 The second is individual reinsurance, which are cost-
465 based payments to plans for which Medicare covers 80 percent
466 of the costs in the catastrophic phase of the benefit.

467 Part B -- Part D spending grew at about 7 percent
468 annually between 2010 and 2017, reaching \$80 billion. But

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469 Medicare's reinsurance payments for Part D enrollees who had
470 drug spending high enough to reach the catastrophic phase
471 grew almost 20 percent annually over the same period. Again,
472 high-cost therapies drive these trends. Part D spending for
473 high-priced specialty tier drugs grew tenfold between 2007
474 and 2017. And, again, this growth is driven by price.

475 In 2017, 370,000 beneficiaries filled a single
476 prescription that was so expensive it would push them into
477 the catastrophic phase of the benefit, up from just 33,000
478 such beneficiaries in 2010.

479 When plans have financial responsibility for insurance
480 risk, they face greater incentives to manage costs. However,
481 growth in reinsurance, recent changes to the coverage gap,
482 and the growth in high-cost medicines may be eroding plans'
483 incentives to and ability to control costs. In fact, Part
484 D's benefit structure may give plans a financial incentive to
485 play certain high-cost, high-rebate drugs on their
486 formularies, even when lower cost alternatives are available.

487 Growth in drug prices substantially affects Medicare
488 drug spending. This growth reflects both higher prices for
489 existing products and the launch of new high-price drugs.
490 Yet, again, Medicare has very limited influence over drug
491 prices.

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492 Recent commission recommendations attempt to address the
493 growth in Medicare drug spending. In Part B we would give
494 clinicians an alternative to the "buy and bill" environment,
495 and provide incentives for them to use this approach.

496 In Part D we would shift more liability for costs in the
497 catastrophic phase of the benefit to plans. In exchange, we
498 would give plans more tools and flexibility to manage
499 enrollees' utilization. We would also eliminate beneficiary
500 cost-sharing in the catastrophic phase.

501 In sum, prescription drugs are essential to treating
502 many medical conditions, and Medicare must ensure that
503 beneficiaries have access to appropriate medication
504 therapies. At the same time, high prices for drugs make it
505 difficult to ensure this access, while protecting the
506 taxpayers and beneficiaries who funds the program. We hope
507 the committee regards the commission as a resource as you
508 develop policies to address these critical issues.

509 Thank you.

510 [The prepared statement of Mr. Matthews follows:]

511

512 ***** INSERT 1 *****

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513 Ms. Eshoo. Thank you, Dr. Matthews.

514 We have now concluded the opening statements and we will
515 move to member questions. Each member will have five minutes
516 to ask questions of Dr. Matthews. And I will start by
517 recognizing myself for five, for five minutes.

518 Again, thank you, Dr. Matthews. In my opening statement
519 I spoke about the increase in spending on specialty drugs.
520 And you, you also have spent part of your testimony on
521 specialty drugs in the Medicare Part D program, and what that
522 means for seniors.

523 You point out that plans may not have the incentive or
524 the ability to control the costs of specialty drugs. So,
525 what, can you restate for us what exactly MedPAC believes
526 what plans can do to better manage the costs of the new
527 specialty drugs?

528 And, of course it is not just Medicare being hit by the
529 trend in high-cost drugs. We have -- well, I have some other
530 questions, too. Maybe I should just put all my questions out
531 and you can answer them.

532 VA, Medicaid, and private plans, how are they managing
533 this trend?

534 How to other federal programs like the VA and TRICARE
535 leverage their buying power for these products?

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536 And what is the effect of high-cost drugs -- well, we
537 know what the effect of high-cost drugs on beneficiaries is.
538 Does MedPAC have a recommendation relative to an out-of-
539 pocket cap needed for Medicare drug costs?

540 I know that you said that Medicare has very little
541 authority relative to pricing but, you know, we want to
542 examine everything, every angle of this Rubik's Cube. And
543 so, if we were to implement such a cap, how would that affect
544 the incentive for drug makers in Part D plans that we have
545 discussed?

546 So, those are my questions. And have at it.

547 Mr. Matthews. Sure. So, and again thank you for the
548 invitation to testify and to clarify. This is my first
549 testimony before Congress.

550 Ms. Eshoo. Oh. Well, bravo. It is not so bad, is it?

551 Mr. Matthews. Not yet.

552 [Laughter.]

553 Ms. Eshoo. This is a friendlier hearing room. It is
554 smaller, it is more personal. So, share your wisdom and your
555 expertise with us.

556 Mr. Matthews. Sure. So, your question has multiple
557 components and I am going to try and get to all of them.

558 First, as you know, Medicare has made a recommendation

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559 in 2016, and slightly modified that recommendation in 2018,
560 to modify the structure of the Part D benefits. And the
561 motivation behind this recommendation hinges on the entry of
562 high-cost, high-rebate drugs into the Part D program, and the
563 incentives that the plans have to place those drugs on their
564 formularies, even when lower cost alternatives are available.

565 And the incentives are such that the plan can move a
566 beneficiary into the catastrophic phase of the benefits where
567 the plan only has 15 percent liability for those costs under
568 current law. The Medicare program is liable for 80 percent,
569 which it makes on a retrospective cost basis. So, it is
570 counter to the incentives that the plans have to actually
571 manage the benefit above the catastrophic limit.

572 Plans are not the only actor that might have a role in
573 managing costs at that level. We have started to evaluate
574 additional reforms to the structure of the Medicare Part D
575 benefit that would contemplate a role for the manufacturer to
576 have some financial responsibility above that catastrophic
577 phase, in contrast to current law where the manufacturer is
578 liable for a 70 percent discount on brand name drugs within
579 the coverage gap.

580 We are contemplating whether or not the incentives might
581 be better for beneficiaries and the program as a whole by

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582 shifting that liability above the catastrophic threshold.

583 Ms. Eshoo. Is there any benefit to the beneficiaries
584 relative to rebates in this?

585 Mr. Matthews. So, we think that by aligning the
586 incentives for the plans and manufacturers to bargain hard
587 for costs and to manage utilization that that would probably
588 have a more direct and immediate effect on the majority or
589 the totality of Part D enrollees relative to rebates that
590 have distorted effects with respect to any individual
591 beneficiary's utilization and costs.

592 Ms. Eshoo. And the other, how the other programs,
593 private plans, Medicaid, VA, how are they managing this
594 trend? How do they leverage their buying power for these
595 products?

596 Mr. Matthews. So, so Medicaid has a couple of tools
597 available to the program. And, again, I am not deep on
598 Medicaid because my expertise is primarily Title 18, so I
599 don't want to stray too far out of what I am able to talk
600 about. But Medicaid benefits from a statutory discount and
601 also from a certain inflation rebate that governs how much
602 manufacturers can increase their prices.

603 VA is able to contract directly with manufacturers and
604 suppliers under the Federal Supply Schedule. They can do so

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605 because they actually take delivery of products and can
606 guarantee utilization. But it is my understanding that
607 sometimes VA has been criticized in that they have a closed
608 formulary that in some cases has precluded access to certain
609 innovative medications.

610 Ms. Eshoo. Well, my time has certainly expired. So now
611 I would like to recognize Mr. Bucshon, who is standing in for
612 the subcommittee ranking member, for his five minutes of
613 questions.

614 Mr. Bucshon. Thank you, Madam Chairwoman.

615 Dr. Matthews, MedPAC in the past has recommended a
616 voluntary market-based program for doctors to use third party
617 vendors to obtain drugs in Part D. The Administration, in
618 its advanced notice of proposed rulemaking, proposes setting
619 up a similar system but would make it mandatory for
620 physicians to participate.

621 I have heard concerns from providers that requiring them
622 to switch to vendors could be very disruptive. Can you
623 discuss why MedPAC opted for a voluntary program, and what
624 features you included to foster competition on drug pricing?

625 Mr. Matthews. Sure. One of the main reasons that led
626 us to recommend a vendor-based approach to Part D drugs was
627 the potential inflationary incentives inherent in Part B.

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628 Where the higher the cost of the drug, the higher the 6
629 percent add-on that the provider who administers the drug
630 receives from the program.

631 And the research is fairly limited as to whether or not
632 providers are actively acting on those incentives but,
633 nonetheless, the incentives are still there. And we feel
634 that getting providers out of the financial incentives
635 related to "buy and bill" would be better served by having
636 them focus more on selecting the drugs that are most
637 appropriate to the given patient.

638 And so, we have recommended a modernization of the prior
639 competitive acquisition program that Medicare used several
640 years back under which a vendor would be responsible for
641 negotiating prices with manufacturers, and the vendor would
642 be able to pass on those prices to the individual clinicians
643 or providers who prescribe drugs under Part B.

644 Mr. Bucshon. Can I ask a question there?

645 Mr. Matthews. Sure.

646 Mr. Bucshon. Because if you add another middle person,
647 just so you are going to -- you might, there might be some
648 savings but you are going to eat some of that up; right?

649 Mr. Matthews. Under our construct there would be a
650 couple of parameters that would govern the ability of a

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651 provider to eat up those savings.

652 One, under our construct savings would accrue to the
653 vendor, and savings would also accrue to the clinicians who
654 voluntarily elected to participate in that vendor's
655 negotiated prices.

656 The second thing that we would do --

657 Mr. Bucshon. So that would be the difference between
658 voluntary and mandatory then essentially; right?

659 Mr. Matthews. Yes, sir, that's correct.

660 Mr. Bucshon. Okay.

661 Mr. Matthews. The second thing we would do is under our
662 recommendation we would have a requirement that the vendor
663 negotiate prices no higher than 100 percent of ASP as
664 currently pertains to the market. So, there would be a
665 couple of ways to govern any potential price increases on the
666 Medicare --

667 Mr. Bucshon. Well, couldn't you, couldn't you just do
668 that? Couldn't we just do that without a vendor in the
669 middle? We could just say we are -- I mean, that has been
670 tried, right? There was a demonstration project?

671 Mr. Matthews. Yes, sir.

672 Mr. Bucshon. In a previous administration cutting it
673 down to ASP plus I think 2 point some percent. I can't

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674 remember.

675 Mr. Matthews. So, the current sequester effectively
676 reduces Medicare payments for Part B drugs from the statutory
677 ASP plus 6 to ASP plus 4.3 percent.

678 Mr. Bucshon. Yeah, yeah.

679 Okay, the demonstration project, which didn't happen, --

680 Mr. Matthews. Right.

681 Mr. Bucshon. -- was even lower than that.

682 Mr. Matthews. Right.

683 Mr. Bucshon. I have another question, so I will move on
684 from there.

685 But first of all, as a physician I think there
686 automatically is an assumption that physicians out there will
687 choose higher price, a higher priced product to make more
688 money. And I will just push back on that and say that I
689 think there are maybe people that would do that. But I would
690 argue that the vast majority of physicians make decisions on
691 which medications to use for patients based on known clinical
692 knowledge based on standard of care in their community. I
693 just want to say that up front.

694 But we do, but there are incentives. Not disagreeing
695 with that.

696 In MedPAC's recommendation for Part D it suggests that

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697 plan sponsors be given more financial incentives to manage
698 the benefits of high-cost enrollees by shifting more of the
699 plan payments from open-ended reinsurance to capitated
700 payments. As part of a -- part of this suggestion, plan
701 sponsors would be given more flexibility to use "formulary
702 tools."

703 As a physician I have had some problems with those
704 "formulary tools" such as step therapy and prior
705 authorization for many years. That could delay patient
706 access to timely medications, disrupt treatment regimens for
707 stable patients and create unnecessary physician burden.

708 Did MedPAC consider these potential impacts to patients
709 and physicians before providing this recommendation?

710 Mr. Matthews. Yes, sir, we did. And, as always, there
711 is a balance or set of tradeoffs involved in these kinds of
712 decisions where you want to give the plans the leverage with
713 manufacturers to negotiate prices and incentive to manage
714 utilization versus any potential speed bumps that those tools
715 put in front of providers and patients in terms of timely
716 access to the medications.

717 So, we have talked with stakeholders in the course of
718 developing our recommendations. And we do understand the
719 frustration that some of these utilization management tools

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720 create. But, at the same time it is a question of the
721 tradeoffs and the balance that we are trying to achieve for
722 the program as a whole.

723 Mr. Bucshon. Okay, great. Thank you. My time has
724 expired and I yield back.

725 Ms. Eshoo. I thank the gentleman and he yields back.

726 The chair now recognizes Mr. Pallone, the full committee
727 chairman, for his five minutes of questioning.

728 The Chairman. Thank you. Thank you, Madam Chair. And
729 I wanted to kind of follow up on some of those things that
730 you mentioned, Madam Chair.

731 Let me start with Part D. MedPAC has analyzed that
732 between 2007 and 2017, Part D program spending increased from
733 \$46 billion to about \$80 billion, for an average increase of
734 5.6 percent per year, which I think is unsustainable. So,
735 Dr. Matthews, can you explain why we are seeing these steep
736 spending increases in Part D?

737 And it is my understanding that a smaller portion of
738 high-cost beneficiaries are driving the majority of Part D
739 spending; and is that correct?

740 Mr. Matthews. Yes, sir, that is correct.

741 As one of the members said in the opening statements,
742 Part D has been successful in shifting a substantial amount

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743 of utilization among Part D enrollees to generics, which the
744 commission has supported. But at the same time, we are
745 seeing the entry of new high-cost specialty drugs into the
746 program. And over the last several years it is those drugs
747 that have been predominantly driving the increases in
748 spending that we have documented.

749 The Chairman. Now, I know you talked a little bit about
750 some of MedPAC's solutions to control spending in response to
751 Chairman Eshoo. But would you, would you develop that a
752 little more? What are some of MedPAC's solutions to control
753 spending in the future?

754 Mr. Matthews. Okay. So, again, under Part D one of the
755 key elements that we would do is restructure the benefit to
756 give plans more of an incentive to manage utilization above
757 the catastrophic limit. We feel that having the program be
758 responsible for 80 percent of those costs above the
759 catastrophic limit is inconsistent with the notion that Part
760 D was founded on, which was that Part D plans would compete
761 with manufacturers in order to generate the best possible
762 price for the enrollees in order to keep premiums low.

763 So, we feel that the incentives currently has negated
764 plans' ability to do that somewhat.

765 As we have been discussing the growth in Medicare

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766 spending for drugs under Parts B and D since then, we have
767 become more attuned to the influence of these new, high-cost
768 therapies. And we are starting, as I said earlier, to
769 contemplate whether or not manufacturers, who do indeed
770 control the price, should have a greater liability for
771 spending in the catastrophic phase of the benefit.

772 Again, the commission has not made any formal
773 recommendation there yet, but it is something that we are
774 very actively engaged in doing.

775 The Chairman. Let me get into two more questions. This
776 is the last one on Part D, then I want to ask about Part B.

777 You talked about generics. You know, we are very proud
778 of the fact that on a bipartisan basis we reported out a
779 package of generic competition bills that I think are going
780 to go to the floor soon. But, of course, if you have these
781 single source drug therapies, there is no competition.
782 Right? So, we know often that these innovative products can
783 change lives, the single source. But without competition how
784 difficult is it to control the cost of those therapies in
785 particular?

786 Mr. Matthews. We believe it is difficult. And that is
787 one factor that has led us to contemplate going further than
788 our 2016 benefit restructuring recommendation. And again,

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789 here the recommendation was to have plans liable for 80
790 percent of those costs.

791 But, if we are talking about true sole-source products
792 for which there are no competitors, the plans are going to
793 have fairly limited negotiating leverage with which to
794 negotiate hard on price with the manufacturers.

795 And that is why we are starting to contemplate whether
796 or not the manufacturers should have some liability for costs
797 above the catastrophic phase.

798 The Chairman. All right. Now let me address Part D.

799 I was struck by the rate of rapid annual growth in Part
800 D drugs mentioned in your testimony, almost 10 percent
801 spending increases annually for the past decade. So, one
802 question.

803 Could you provide some examples of the most expensive
804 drugs in the Part D program and the conditions they treat?
805 And what are some of the annual per-user costs for these
806 drugs? And what is the beneficiary's responsibility for
807 these costs?

808 Mr. Matthews. Sure. And just to clarify, this is D?

809 The Chairman. D now. This is my only question about D,
810 yes.

811 Mr. Matthews. Yes, of course.

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812 So, a lot of the high-cost drugs that we have been
813 seeing over the last several years are high-cost specialty
814 drugs, predominantly biologics. All of the top ten drugs for
815 Part D in terms of spending are biologics. They are used to
816 treat conditions such as cancer and its side effects,
817 rheumatoid arthritis, and ocular conditions such as macular
818 degeneration.

819 The Chairman. All right. Thank you so much.

820 Thank you, Madam Chair.

821 Ms. Eshoo. I thank the gentleman, and he yields back.

822 The chair now recognizes Mr. Walden, the full committee
823 ranking member for his five minutes.

824 Mr. Walden. Thank you, Madam Chairwoman.

825 And again, Doctor, thank you for the work you do, and
826 your team.

827 We know that a lot of surveys show seniors like Medicare
828 Part D, like a 90 percent approval rating. But we also see
829 some disturbing trends. And I wanted to ask you about some
830 of that.

831 I hear a lot about the rising out-of-pocket costs for
832 seniors. And I have some concerns that some of the changes
833 to the Part D program provide incentives to use brands over
834 generics, and particularly as it relates to true out-of-

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835 pocket cost, the acronym TrOOP, calculations.

836 So, if a senior used only generics they would have to
837 spend about \$5,100 to reach the catastrophic stage of
838 coverage; correct?

839 Mr. Matthews. Yes, sir. That sounds about right.

840 Mr. Walden. And so, due to the way TrOOP is calculated,
841 I am told a senior would have to spend only \$2,275 in a year
842 to reach catastrophic coverage if they use only brands. Is
843 that?

844 Mr. Matthews. Without commenting on the specific dollar
845 amounts, I believe the proportions are correct.

846 Mr. Walden. Okay. And how have these incentives then
847 affected Part D formularies and plan design? What is
848 happening in this?

849 Mr. Matthews. So, we do see a trend where plans have in
850 certain instances included high-cost, high-rebate drugs on
851 their formularies even when lower cost alternatives are
852 available.

853 And the idea here is that the high-cost drug is going to
854 get the beneficiary into the coverage gap sooner than a lower
855 cost brand name drug, or a lower cost generic. And it is
856 above the coverage gap in the current construct where the
857 plan only has 15 percent liability for those costs.

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858 And so, arguably, there are instances where the size of
859 the rebate for certain drugs can be so great as to even begin
860 to offset their 15 percent liability above that catastrophic
861 limit.

862 Mr. Walden. So, what is the effect for taxpayers, and
863 what is the effect for consumers for that?

864 Mr. Matthews. So, for taxpayers then the fastest
865 growing component of Medicare spending for Part D is the
866 reinsurance payments that the program makes to plans. And
867 these are payments that reflect plans' costs for these
868 extremely high-cost enrollees. But these payments are also
869 funded directly by the Medicare program.

870 So, the fact that these reinsurance payments have been
871 growing for 20 percent year over year for the last ten years
872 is detrimental to taxpayers. And to the extent that these
873 costs are reflected in the calculation of Part B premiums, it
874 is detrimental for the beneficiaries who are paying for these
875 premiums.

876 Mr. Walden. All right, thank you very much. I will
877 yield back, Madam Chair.

878 Ms. Eshoo. I thank the gentleman. Yields back.

879 The chair now recognizes the gentlewoman from
880 California, my friend Congresswoman Matsui.

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881 Ms. Matsui. Thank you so much, Madam Chair.

882 And thank you, Dr. Matthews for joining us today.

883 While it is important to focus on lowering the price of
884 prescription drugs to patients and to ensure the
885 sustainability of the Medicare program, we can't lose sight of
886 the need to protect beneficiaries' access to necessary
887 medications. As you know, the Administration last fall
888 proposed changes to the protected class policy that would
889 allow Part D plan sponsors to add restrictions or otherwise
890 limit prescription medications in the six protected classes.

891 The protected class policy is an important safety net
892 for patients who absolutely need potentially life-saving
893 medications to treat a complex medical condition. I am
894 particularly concerned that changing protected class policy
895 will jeopardize Medicare beneficiaries' access to the full
896 range of medicines for treating mental illness.

897 For example, antidepressant medication impacts
898 individuals differently and, as such, can take time to find
899 the right treatment that works for any given individual. And
900 earlier this month I wrote a letter to my colleagues to CMS
901 expressing this concern.

902 Dr. Matthews, I understand that MedPAC has recently
903 considered similar changes to two of the six protected

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904 classes, including antidepressants. Given my concern around
905 access for Medicare's most vulnerable beneficiaries, I am
906 interested in your thoughts on how we can continue to ensure
907 the availability of needed medications while making changes
908 to protect the classes?

909 Mr. Matthews. Sure. Yes, ma'am, I'm happy to address
910 that.

911 As part of our 2016 recommendations on Part D, we did
912 recommend removing two categories of drugs from the protected
913 classes, one of which was antidepressants. The second one
914 was immunosuppressives used after transplant surgery.

915 The rationale here was that there do seem to be enough
916 alternatives in those two categories that plans could be able
917 to put together a formulary that accommodated the clinical
918 needs of most beneficiaries needing those drugs without being
919 constrained by having to cover every drug on those protected
920 classes.

921 The Administration's proposal is a little bit different.
922 I don't think they have recommended eliminating any of the
923 protected classes, but have proposed giving plans more
924 ability to use utilization management within those classes.

925 Again, you know, the balance here is beneficiary access
926 relative to plans' ability to negotiate with manufacturers

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927 for price. And if the plan has to cover every single drug in
928 a protected class, they have virtually no leverage in order
929 to negotiate with a manufacturer. So, it is those tradeoffs
930 that led us to the recommendation.

931 The last thing I would say is we would, in either
932 instance, in our recommendation or with respect to the
933 Administration's proposal, we would believe that there is a
934 strong need for a well-functioning appeals process that
935 beneficiaries can avail themselves of.

936 Ms. Matsui. I agree. Yeah, that would be good.

937 But on the other hand, you know, we have had experience
938 with people with mental illness. And in particular, as you
939 know, the therapy involved there is very difficult to get the
940 right medication. And then to have to go back again to start
941 over since there we know that is not going to work anyway.
942 And I just really hope that whatever process you decide to
943 implement is really going to be very sensitive to that.

944 Because we would hate to lose the ability for
945 individuals who already found a therapy to be able to
946 continue in some way.

947 Mr. Matthews. Yes. We are keenly aware of the unique
948 nature of treatments for behavioral disorders.

949 Ms. Matsui. Okay. I want to talk a little bit about

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950 out-of-pocket spending for beneficiaries in Medicare Part D.
951 And I am concerned about patient access issues created by the
952 fact the Part D program does not currently have an out-of-
953 pocket limit. It means that some seniors who have
954 significant drug spending, often those with chronic diseases
955 or those who are severely ill, will continue to pay a cost-
956 sharing obligation even in the catastrophic phase, and even
957 after spending thousands of dollars out of pocket.

958 I know that MedPAC has recommended reforming the Part D
959 benefit to eliminate cost sharing above the out-of-pocket
960 threshold. Can you explain MedPAC's recommendations to cap
961 out-of-pocket expenses for Part D beneficiaries, and how this
962 change might impact premiums and other aspects of the benefit
963 design?

964 And I only have about 15 seconds here.

965 Mr. Matthews. Sure. So, we did indeed recommend in
966 2016 capping the beneficiary's financial obligation above the
967 catastrophic phase. The motivation was that if the
968 beneficiary is incurring that kind of cost, coinsurance is
969 not a drag on inappropriate utilization but it is potentially
970 punitive at that point from the beneficiary's financial
971 perspective.

972 Ms. Matsui. Okay. I yield back my time. Thank you.

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973 Ms. Eshoo. I thank the gentlewoman. She yields back.

974 I now would like to recognize the gentleman from
975 Illinois, Mr. Shimkus, for five minutes of questions.

976 Mr. Shimkus. Thank you, Madam Chairman. And I want to
977 thank you for having this hearing today.

978 Dr. Matthews, welcome. We appreciate your input. And
979 it is very helpful. We just need to take action, and that is
980 what this hearing is.

981 I also appreciate your comments on trying to clarify the
982 how is VA different. I know that is kind of out of your
983 window. But, that there is a formulary and so the formulary
984 is narrow, so even our veterans may not get the full scope of
985 drugs available in our country because they are purchasing
986 and making contracts. And we always have to try to explain
987 that in this process because sometimes it gets lumped
988 together and say, well, why can't you do it that way? And I
989 guess if you have lower cost, that is good. But if you don't
990 get the drug, the blockbuster drug, then it is bad. So, then
991 there is, there is that balance.

992 I also appreciated, talking just Medicare D, what
993 benefit was provided to our seniors for health and
994 prescription drugs prior to Medicare D?

995 Mr. Matthews. There was no real outpatient prescription

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996 drug benefit.

997 Mr. Shimkus. There was none. So, I mean, again, for,
998 just for an instruction purpose, we wrestled with how to get
999 Medicare. In fact, a lot of conservative Republicans got
1000 beat up quite a bit on this because we expanded in essence an
1001 entitlement and mandatory spending program. But modern
1002 medicine said prescription drugs has to be part of the fix.

1003 I know the chairman has left, but we had some great
1004 fights, and debates, and battles. And Chairman Pallone was
1005 most angry about the donut hole provisions which we placed in
1006 there for budgetary -- to make the numbers work.

1007 So, I was surprised when I met with a constituent
1008 because I don't follow this as closely as you all do, and we
1009 have a new world of drugs on the market prior to what we did
1010 in 2003. They are lifesaving drugs, they are biologics, they
1011 are especially new blockbuster drugs are very, very
1012 expensive.

1013 So, I had a constituent who provided me with this, a
1014 biologic. It is actually ant -- let me look down there.
1015 What was it? Enzyme. Come on, come up here so you can tell
1016 me. All right, enzyme deficiency. So, this is at a cost a
1017 year of \$348,000.

1018 So, then I was kind of going through how Medicare D got

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1019 established. And I drew the donut hole. I said, you pay
1020 here, you fall into the donut hole, you have to pay it all.
1021 And then it was our intent that once you came out of the
1022 donut hole that you would be covered. So, I think some of
1023 your proposals are trying to address, well, you know, the
1024 answers to Doris, Congresswoman Matsui's concerns about end
1025 of out-of-pocket cost.

1026 And then I was surprised when he provided me information
1027 that the percentage cost. This is 22,000, 348,000 over a
1028 year, 22,000 a month. They are still on the hook for a
1029 percentage of that.

1030 Mr. Matthews. Yes, sir. Correct.

1031 Mr. Shimkus. So for those who were in that room in 2003
1032 thought that once they got out of the donut hole they had
1033 kind of gotten home free. That is not true, is it?

1034 Mr. Matthews. No, sir, it is not.

1035 Mr. Shimkus. Yeah, and it is not true for my
1036 constituent either. So, I appreciate him meeting me. We
1037 actually met in a bar, you know, as I was traveling through
1038 my district, which is very large. Yeah, we did have to have
1039 a few drinks after I heard that cost of that, they were
1040 having the burden.

1041 So, we need to address this, you know, this major

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1042 expense. And if Medicare D is supposed to be an insurance
1043 plan and then there is a catastrophic portion, there is
1044 eventually a time when -- and I think that is your
1045 reinsurance provision and those other proposals, am I
1046 correct?

1047 Mr. Matthews. That's correct. Yes, sir.

1048 Mr. Shimkus. So, I just thank you for being here. It
1049 is my understanding that you are an independent agency and
1050 you advise us. So, I would hope, Madam Chairman, that we
1051 would take your counsel and try to address especially this
1052 end of the process because Medicare D does -- seniors pay in.
1053 I mean, so they are part of the solution. They are not just,
1054 it is just not all government solution because it is an
1055 insurance plan that they are partners with and they choose.
1056 We need to help them on the back end.

1057 So, with that I appreciate your time. Thank you, Madam
1058 Chairman. And my time has expired.

1059 Ms. Eshoo. I thank the gentleman. Excellent questions.

1060 I now would like to recognize the gentleman from Oregon,
1061 Mr. Schrader, for five minutes of questions.

1062 Mr. Schrader. Thank you, Madam Chairwoman, I appreciate
1063 it.

1064 Dr. Matthews, thanks -- I need some medication myself --

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1065 thank you for taking time to be here.

1066 As you may or may not know, my State of Oregon is taking
1067 steps to increase the number of payments tied to performance
1068 in Medicaid. Specifically, they are using an 1115 waiver to
1069 work with our coordinated care organizations and network
1070 providers to create a plan to have a value-based payment by
1071 2022. Other states are also trying to set up these
1072 arrangements.

1073 Has MedPAC evaluated either in specific cases or more
1074 broadly whether Medicare may benefit from value-based
1075 payments and tying the reimbursement to actual outcomes?
1076 What, if any, barriers are in the way for that?

1077 Mr. Matthews. So, we are aware of the emergence of
1078 these types of value-based arrangements, both here in the
1079 United States and in European countries. It is my
1080 understanding that the evidence on the long-term
1081 effectiveness of these arrangements simply does not yet
1082 exist, that these are new enough that a broad base of
1083 evidence hasn't been generated to ascertain that they have,
1084 they can exercise the potential that the stakeholders believe
1085 is there.

1086 With respect to Medicare, one potential impediment to
1087 the broad use of these sorts of value-based arrangements is

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1088 the voluntary nature of Part D. So, a plan may enter into a
1089 manufact -- an agreement with a manufacturer that is
1090 contingent on certain beneficiary outcomes that may not
1091 manifest themselves until after the lapse of a period of
1092 years. But Part D is a voluntary benefit, and a beneficiary
1093 can move from one plan to the next year after year. And so,
1094 a plan may not see the benefits of its investment in these
1095 arrangements for a particular enrollee.

1096 So that is one potential logistical obstacle in Part D
1097 as currently designed.

1098 Mr. Schrader. Good point.

1099 With regard to the general Medicare population, you
1100 spoke in your testimony about the long-term beneficiaries
1101 disproportionally selecting brand drugs sometimes over
1102 generic, actually oftentimes brand over generic. What remedy
1103 for increasing utilization of generics by this population
1104 would you recommend? I know that there are administrations
1105 out there trying just to lower the cost of the brands or,
1106 excuse me, the generic to zero to make it appealing. What
1107 about increasing the cost of the brand? Your thoughts.

1108 Mr. Matthews. So, we have gone on record as
1109 recommending that even low income or beneficiaries receiving
1110 the low income subsidy should be given incentives to use

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1111 generics when they are available and clinically appropriate.

1112 As you just mentioned, those incentives can take one of
1113 two forms: one is zero copayments or zero financial liability
1114 for generics; the second would be some nominal financial
1115 liability for the use of brand name drugs when generics are
1116 available. And we think that even low income beneficiaries
1117 should have to make those kinds of decisions with respect to
1118 the therapies that they and their clinicians decide on.

1119 Mr. Schrader. So you don't have an opinion as to
1120 whether just reducing one or increasing?

1121 Mr. Matthews. Either would achieve the goal of
1122 increasing benefi -- low income beneficiaries' use of
1123 generics.

1124 Mr. Schrader. All right. Very good, thank you.

1125 With that, I yield back.

1126 Ms. Eshoo. I thank the gentleman. He yields back.

1127 I now would like to recognize the gentleman from
1128 Kentucky, Mr. Guthrie.

1129 Mr. Guthrie. Thank you, Madam Chair, for holding this
1130 meeting.

1131 And thank you for being here. Doing a good job for your
1132 -- good job even though it is your first time. I almost said
1133 a good job for your first job. But a good job. I appreciate

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1134 it very much.

1135 And, unfortunately, we should coordinate better with my
1136 neighbor in the hallway Mr. Schrader because he asked almost
1137 word for word one of the questions I was going to ask. So,
1138 let me get to the valued-based. That is interesting to me.

1139 But so, are you supportive of transparency tools like
1140 realtime prescription benefit check that could help
1141 beneficiaries understand the cost of their prescribed
1142 medications before they leave the doctor's office?

1143 Mr. Matthews. Yes, sir. We have been supportive of
1144 clinicians' use of electronic tools like realtime benefit
1145 check.

1146 Mr. Guthrie. So, what policies do you think we should
1147 develop to encourage use of these policies, of these tools?

1148 Mr. Matthews. I would need to think about that, with
1149 all due respect. It is my understanding that the technology
1150 does exist with respect to currently available electronic
1151 health records. But the issue is getting the clinician to
1152 actually purchase the requisite models or modules to do the
1153 realtime benefit check, and providing incentives for
1154 clinicians to use those.

1155 The commission does not have a specific proposal in
1156 order to do that.

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1157 Mr. Guthrie. Okay. Thank you.

1158 And changing gears, since Mr. Schrader took my thunder,
1159 I am told that the physician charge, I am told that a
1160 physician charges, that a physician charges per administering
1161 drugs are twice as much in hospitals compared to doctors'
1162 office. This drives up Medicare costs but also drives up
1163 cost-sharing for the patients. Can more be done to address
1164 this through site neutral payment reform?

1165 Mr. Matthews. Yes, sir. I believe there is more that
1166 can be done. As you know, the commission has been concerned
1167 about the incentives or the undesirable incentives that occur
1168 with respect to the differential for a clinician's services
1169 in the physician office versus the hospital outpatient
1170 department. And we have made recommendations to standardize
1171 those payments across settings.

1172 Yet, nevertheless, we think that those incentives still
1173 exist and that there are potential broader remedies that
1174 could be contemplated.

1175 Mr. Guthrie. Okay, thank you. And, again, thanks for
1176 being here today, and holding the hearing. And I yield back.

1177 Mr. Bucshon. Will the gentleman yield for a few
1178 seconds.

1179 Mr. Guthrie. Yes, I will yield the remainder of my time

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1180 to Mr. Bucshon.

1181 Mr. Bucshon. Yeah, yeah.

1182 Mr. Guthrie. Dr. Bucshon.

1183 Mr. Bucshon. Yeah. I just want to make a brief comment
1184 on what he was talking about about the patients knowing up
1185 front what prices drugs are.

1186 When I was in practice, if I was going to prescribe
1187 something I knew might cost a lot I actually checked myself
1188 personally before I would prescribe it for the patient, just
1189 to make sure. But I do think in today's electronic world
1190 that we should, physicians should be able to determine that
1191 up front. And sometimes, depending on the patient, that may
1192 very well make you make different decisions on what the
1193 options are because if the out-of-pocket is going to be real
1194 high to the patient there might be therapeutic alternatives.

1195 So, I do think we can get to a place where electronic
1196 records can provide that information at a minimum to the
1197 provider. I think it is when you go to the consumer it is
1198 more confusing, but for the provider I think that can, that
1199 could help, so. Yeah, it could pop up on the screen for
1200 example when you go to provide, when you go to send an
1201 electronic prescription.

1202 So, I yield.

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1203 Mr. Guthrie. Thanks. I yield back.

1204 Ms. Eshoo. I thank the gentleman. And he yields.

1205 I now would like to recognize the gentleman from
1206 California, Dr. Ruiz, for five minutes of questioning.

1207 Mr. Ruiz. Thank you.

1208 Dr. Matthews, I appreciate the position that the
1209 commission is in trying to make recommendations that balance
1210 the need to cut down on health care costs while also ensuring
1211 that patients are getting the care that they need. And I
1212 know that patient care is important to you.

1213 In your written testimony you identify one of the
1214 commission's goals is "achieving a Medicare program that
1215 ensures beneficiary access to high quality, well-coordinated
1216 care."

1217 Last November, CMS proposed a rule that would allow
1218 Medicare Advantage plans to use step therapy for Medicare
1219 Part B drugs. And, while I understand that step therapy can
1220 play an important role in reducing health care costs, it
1221 often does not take into account a patient's medical history,
1222 like whether they have tried the medication previously and
1223 failed under a different insurance plan.

1224 Fred Sangiorgio, one of my constituents from La Quinta,
1225 California, suffers from psoriasis and psoriatic arthritis

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1226 and is going through step therapy right now. He has been
1227 diagnosed most of his adult life and has tried several
1228 treatments over the years. Despite the fact that he already
1229 tried one treatment that didn't work, he is currently being
1230 forced to go through a similar treatment that his doctor
1231 knows won't be effective.

1232 Instead of being able to prescribe an alternative
1233 treatment that she thinks will be more effective, his doctor
1234 has to wait for this drug to fail, too, despite the fact that
1235 both of them know that what is going -- what is going to
1236 happen.

1237 That is why I have introduced legislation with my friend
1238 Congressman Wenstrup, a fellow physician, that would help
1239 protect the doctor/patient relationship and help get patients
1240 the care that they need. The Safe Step Act creates a list of
1241 exemptions that will allow patients to bypass step therapy if
1242 their doctor knows that the treatment will not be successful,
1243 as is the case with Fred.

1244 As a physician, I want to ensure that all step therapy
1245 protocols also include safeguards to help ensure that
1246 patients aren't forced to have to try a treatment that their
1247 provider knows is not likely to work for them, or even to
1248 take a drug that may have already failed for them in the

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1249 past.

1250 So, can you outline some safeguards that CMS can put
1251 into place to protect the patients from unnecessary and
1252 potential harmful treatments?

1253 Mr. Matthews. Yes, sir. So, again, the commission has
1254 gone on record as supporting giving plans more flexibility to
1255 appropriately use these management tools. We do understand
1256 that the circumstances of every patient is unique and that we
1257 would not support putting a patient through some of these
1258 things, like step therapy, when the clinician knows that they
1259 are not going to be effective for a given patient. And,
1260 therefore, we have said that the greater use of these tools
1261 has to be accompanied by a very robust and effective system
1262 of grievances and appeals whereby a clinician can request an
1263 expedited --

1264 Mr. Ruiz. So what are some of these exceptions that you
1265 would propose to safeguard patient access?

1266 Mr. Matthews. So, if the clinician is able to document
1267 that the patient has previously failed on a therapy that is
1268 required by a plan's formulary or step therapy or --

1269 Mr. Ruiz. And what does "failed" mean to you?

1270 Mr. Matthews. That the patient's clinical condition has
1271 not responded to the treatment that is being required by the

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1272 plan.

1273 Mr. Ruiz. Does a lack of compliance due to cumbersome
1274 regiments like a, you know, every four hour treatment and,
1275 therefore, that doesn't fit that person's life or work
1276 schedule, would that be considered failure to you?

1277 Mr. Matthews. I do not have the clinical basis to
1278 answer that question, with all due respect. And the
1279 commission hasn't opined at that level of detail.

1280 Mr. Ruiz. Right. In my medical opinion, when it is a
1281 compliance issue it is usually a failure in the system to
1282 provide the best treatment and follow-up for that patient.
1283 It is not the patient's fault per se, which is normally what
1284 happens in the medical world.

1285 So, what other safeguards could we think of that would
1286 provide these exceptions so that we can preserve the
1287 patient's and the physician's judgment in getting them the
1288 medication that is best for that patient instead of putting
1289 them through a rigorous bureaucratic step process in order to
1290 save the company money?

1291 Mr. Matthews. Again, if I could ask for the
1292 dispensation to think about that and follow up.

1293 Mr. Ruiz. Okay. What's the MedPAC strategy to both
1294 monitor beneficiary impact and to ensure CMS institutes

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1295 appropriate safeguards, including those that are lined with
1296 number of state laws which serve as models for the Safe Step
1297 Act?

1298 Mr. Matthews. So, we believe that the Medicare program
1299 is currently monitoring beneficiaries' appeals under Part D.
1300 There are a number of steps that patients and their
1301 clinicians can go through. And it is my understanding that
1302 the majority of those appeals are indeed adjudicated in favor
1303 of the patients when clinically warranted.

1304 So, the agency is indeed monitoring whether or not
1305 beneficiaries' access to medications under Part D as being
1306 unduly compromised.

1307 Mr. Ruiz. Thank you.

1308 Ms. Eshoo. The gentleman yields back.

1309 I now would like to recognize the gentleman from
1310 Florida, Mr. Bilirakis, for five minutes of questioning.

1311 Mr. Bilirakis. Thank you, Madam Chair. Appreciate it
1312 very much. Thanks for holding this very important hearing.
1313 I appreciate it.

1314 Dr. Matthews, with Florida's traditionally higher senior
1315 population, lowering prescription drug prices, as you can
1316 imagine, and Medicare is very important to me. As noted in
1317 MedPAC comments on the International Pricing Index, or IPI

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1318 for short, last year the drug value program recommended
1319 previously by MedPAC would give vendors tools to negotiate
1320 lower prices.

1321 Under the Administration's IPI proposal they don't
1322 include these tools. So it seems like, instead, the
1323 government is just setting the price directly. Am I correct
1324 in concluding that MedPAC's proposal is more market-based
1325 than the Administration's?

1326 Mr. Matthews. I would not want to comment on whether or
1327 not the competing proposals are more market based, one
1328 relative to the other. We did identify a number of potential
1329 logistical issues with respect to the Administration's
1330 proposal that we believe would make it very difficult to
1331 implement. And these range from things such as the one you
1332 just mentioned, that the vendor would not have any tools,
1333 such as a formulary, or other mechanisms by which to
1334 negotiate with manufacturers.

1335 The vendor under the Administration's model would take
1336 title to the drugs, but perhaps not actual physical
1337 possession.

1338 And then, lastly, the vendor would be paid at a rate
1339 determined by Medicare based on the international price
1340 comparison, whether or not they were able to obtain that rate

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1341 on the market or not. And we identified a number of issues
1342 that would affect the ability to even calculate that
1343 international sales rate, given available data and given the
1344 idiosyncratic arrangements between manufacturers and, you
1345 know, other countries' governments.

1346 So, we think there are some substantial implementation
1347 difficulties with respect to the IPI proposal that do not
1348 present themselves under our proposal, which would give the
1349 vendor more ability to negotiate on the basis of being able
1350 to help drive manufacturers's volume.

1351 Ms. Eshoo. Excuse me, Doctor. May I please, I just
1352 learned that your voice is not carrying well on T.V. So, can
1353 you bring your microphone much closer.

1354 Mr. Matthews. Sure.

1355 Ms. Eshoo. And then maybe the staff hearing me will
1356 come back in and let us know if you can be heard.

1357 Mr. Matthews. Thank you.

1358 Ms. Eshoo. Thank you.

1359 Mr. Matthews. Sure.

1360 I am sorry, so I was indicating that under our proposal
1361 that some of the difficulties engendered by the IPI proposal
1362 would be mitigated. And we believe that it would have
1363 greater potential to reduce spending for Part B drugs.

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1364 Mr. Bilirakis. Very good.

1365 I know there are examples in the market where
1366 arbitration is used, such as baseball. I am a big baseball
1367 fan. But developing breakthrough medicine is a lot different
1368 from developing starting pitching. And legislating a
1369 government-defined arbitration process is a lot different
1370 from negotiating one through a players' union.

1371 Mr. Matthews. Yes, sir.

1372 Mr. Bilirakis. Are there examples of binding
1373 arbitration between being used in health care? And do any of
1374 these examples involve setting prices at a national level or
1375 just resolving disputes at an individual level?

1376 Ms. Eshoo. Move your microphone even closer please.
1377 Yeah, pull it right up.

1378 Mr. Matthews. This is, yes, this is not a natural thing
1379 for me to be doing. So I apologize.

1380 Ms. Eshoo. That is all right. We will guide you. It
1381 is just a microphone; get it as close as possible so --

1382 Mr. Matthews. All right.

1383 Ms. Eshoo. -- anyone in the country that is listening
1384 in can actually hear you.

1385 Mr. Matthews. Yeah. That is not helping but I will --

1386 Ms. Eshoo. Okay.

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1387 [Laughter.]

1388 Mr. Matthews. We will see.

1389 So, we are unaware of the use of baseball arbitration in
1390 the way we have proposed it for Part B.

1391 Mr. Bilirakis. Can you describe how you have proposed
1392 it, the arbitration?

1393 Mr. Matthews. Right. So, so as I mentioned both in my
1394 written testimony and in my oral remarks, one of the
1395 vulnerabilities of the Medicare program is that it has
1396 little, if any, ability to influence the price that the
1397 manufacturer sets for a product and, therefore, the price
1398 that Medicare pays. And we believe that binding arbitration
1399 would give the program a means of influencing that price by
1400 bringing the manufacturer to the table with their absolute
1401 best offer for a new product.

1402 And then the secretary would be able to make a competing
1403 offer if he or she did not think that the evidence supported
1404 that manufacturer's price. And that this would be distinct
1405 from a scenario where the secretary is negotiating directly
1406 with manufacturers for price in that only certain drugs that
1407 met a criteria defined under statute or regulation would
1408 trigger this binding arbitration process.

1409 But currently the Medicare program has virtually no

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1410 means whatsoever to influence price. And as I have said in
1411 my testimony, under both B and D price is one of the major
1412 drivers of Medicare spending for drugs.

1413 Mr. Bilirakis. Very good. Thank you.

1414 I yield back, Madam Chair.

1415 Ms. Eshoo. The gentleman yields back.

1416 And I now would like to recognize the gentlewoman from
1417 New Hampshire, Congresswoman Kuster.

1418 Ms. Kuster. Thank you very much. I am delighted to be
1419 here. And thank you for your discussion. It is actually
1420 very, very helpful on a complicated topic.

1421 So, in New Hampshire the nearly 300,000 Medicare
1422 beneficiaries, and most of them, many of them do have
1423 Medicare Part D for complete drug coverage. But the prices
1424 that Granite Staters are facing for prescription drugs are,
1425 to say it bluntly, unacceptable and, frankly, unsustainable.
1426 They are unsustainable for aging communities that rely on
1427 Medicare to be there for them when they turn 65, and for the
1428 taxpayers who hard-earned dollars go toward the different
1429 payment mechanisms that you have walked us through today.

1430 So, I am going to cut to the chase. I want to
1431 understand specifically on the "buy and bill" program.

1432 Under the current Part B system, a provider is

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1433 reimbursed at 106 percent of the average sales price,
1434 regardless of the actual price that they pay for the drug.
1435 And so my question is some providers may be getting the drug
1436 at a price below the average, and it is possible that some at
1437 a price above the average.

1438 Could you explain the original intent behind the 100
1439 percent plus 6 add-on payment? And what information is
1440 available on the provider's actual acquisition cost, what
1441 they pay for the drug?

1442 Mr. Matthews. Okay, sure. I will try to answer without
1443 deigning congressional intent behind the 6 percent add-on.

1444 But, the answer to the question, in all candor, is not
1445 clear. There are a number of competing alternative
1446 explanations for 6 percent. One is that the 6 percent helps
1447 compensate clinicians and providers for the costs of
1448 administering the drug. But, as I mentioned earlier,
1449 Medicare pays the clinician separately for that.

1450 Ms. Kuster. But they get a separate payment for that?

1451 Mr. Matthews. That is correct.

1452 Ms. Kuster. Right.

1453 Mr. Matthews. So, I don't think that explanation is
1454 quite right.

1455 Another explanation is that the 6 percent compensates

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1456 for the provider's costs related to handling and storing the
1457 drug or waste that occurs during the administration of the
1458 drug. But, again, under both the outpatient perspective
1459 payment system and the physician fee schedule there are
1460 components of those payments that reflect providers' costs of
1461 basically running the operation. So I don't think that is -
1462 -

1463 Ms. Kuster. The normal overhead.

1464 Mr. Matthews. That is, that is exactly right.

1465 Ms. Kuster. Exactly.

1466 Mr. Matthews. Yes, ma'am.

1467 And so the most compelling explanation, from my
1468 perspective, is that as you just pointed out, not every
1469 purchaser is able to get the drug at the average price. Some
1470 are paying more, some are paying less. And to the extent
1471 that volume is driving a provider's ability to obtain a good
1472 price, some small, independent practitioners, rural
1473 physicians, small hospitals, may not be getting quite a good
1474 a deal as larger health systems. And so the 6 percent add-on
1475 could be reflecting the relative purchasing provider base --
1476 power based on volume.

1477 Ms. Kuster. So, I am glad you brought up volume. And
1478 my goal is to have the lowest price for the senior and the

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1479 lowest price for the taxpayer. And I think right now it is
1480 safe to say seniors are paying too much, taxpayers are paying
1481 too much.

1482 So, my question is has MedPAC ever examined the impact
1483 on the cost of medications to beneficiaries in the Medicare
1484 program by authorizing Health and Human Service secretary to
1485 negotiate a volume discount on prescription drugs? And have
1486 you ever provided recommendations? Could you tell us?

1487 I just don't understand, everywhere else. I have sat
1488 for six years on the Veterans' Affairs Committee. I know
1489 what federal employees. I know what Walgreen's. And my
1490 constituents don't understand why wouldn't we have a volume
1491 discount for the purchase of medication under Medicare?

1492 Mr. Matthews. The commission has not taken a position
1493 on this issue, nor have we made any recommendations.

1494 Ms. Kuster. So, we don't know, it could bring down the
1495 cost for both the taxpayers and seniors?

1496 Mr. Matthews. I don't know that I would opine on that
1497 myself because the notion of volume discount in some ways
1498 raises the question of the secretary negotiating with
1499 manufacturers and basically saying, I, the Medicare program,
1500 am going to guarantee a certain amount of volume of your drug
1501 and, therefore, you need to give me this volume discount or

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1502 this lower price.

1503 And, again, the commission has not taken a position with
1504 respect to the secretary's ability to influence price through
1505 direct negotiation.

1506 Ms. Kuster. I would simply say, in every other aspect
1507 that is how we bring down the price is negotiating a volume
1508 discount.

1509 So, I very much appreciate your candor.

1510 Mr. Matthews. Sure.

1511 Ms. Kuster. And I yield back.

1512 Ms. Eshoo. The gentlewoman yields back.

1513 I now would like to recognize the gentleman from
1514 Georgia, Mr. Carter, for five minutes of questioning.

1515 Mr. Carter. Thank you very much, Madam Chair. And
1516 thank you, Dr. Matthews, for being here. And thank you for
1517 the work that you in leading MedPAC and helping and doing
1518 your best to keep prices down, as well as providing the best
1519 services that we can to the recipients of Medicare. It is
1520 extremely important.

1521 Earlier this month in this committee, in a bipartisan
1522 fashion, I was able to pass legislation that I sponsored,
1523 bipartisan legislation, along with Representative Gianforte,
1524 Representative O'Halleran, Representative Welch, called the

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1525 Payment Commission Data Act.

1526 Mr. Matthews. Yes, sir.

1527 Mr. Carter. Which is going to allow MedPAC, as you
1528 know, to be able to get data relating to prescription drug
1529 pricing. And you in turn will be able to use that data to
1530 make recommendations to us here in Congress.

1531 Can you just comment on that firsthand on how that may
1532 be able to help you?

1533 Mr. Matthews. Yes, sir. And before I do, I would want
1534 to express on behalf of the commission my appreciation to you
1535 and the other cosponsors of this legislation.

1536 One of the ways that the commission has been hamstrung
1537 in terms of being able to evaluate the effects of the various
1538 rebate structures on the Medicare program and its
1539 beneficiaries is we do not have access to that level of
1540 granular data with respect to rebates on a prescription by
1541 prescription or drug by drug basis.

1542 And so, for example, when we commented on the Office of
1543 Inspector General's recent proposal to eliminate rebates in
1544 the Medicare program we were only able to evaluate that
1545 proposal through its aggregate impacts on the program, on
1546 beneficiaries and manufacturers. We simply did not have the
1547 level of detail in order to be able to assess it would affect

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1548 this group of beneficiaries who are taking this class of
1549 medications for this variety of conditions. And so, having
1550 this more granular data on rebates would help us do those
1551 kind of analyses and help inform the kinds of deliberations
1552 that the committee is having on a regular basis.

1553 Mr. Carter. Right. And I certainly think both of us
1554 would be remiss if we did not mention that that information
1555 is only going to go to you.

1556 Mr. Matthews. Yes, sir.

1557 Mr. Carter. You are the only ones who are going to see
1558 it. It is not -- we get it, it is proprietary information,
1559 but it is not going to be released to the public, it will
1560 only go to the commission.

1561 Mr. Matthews. That is correct, sir. MedPAC has a
1562 sterling track record in terms of --

1563 Mr. Carter. Right.

1564 Mr. Matthews. -- handling proprietary and sensitive
1565 data.

1566 Mr. Carter. Right.

1567 I want to ask you about the DIR fees. You are familiar
1568 with DIR fees and you are familiar with what the
1569 Administration, what Health and Human Services, CMS
1570 specifically, has proposed in changing the rules so that, so

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1571 that DIR fees or discounts will go directly at the point of
1572 sale, as you mentioned earlier. But there were two things
1573 that you mentioned in your letter to the Administration, or
1574 to HHS, about DIR fees, first of all, that DIR fees had grown
1575 from \$229 million in 2013 to \$4 billion in 2017.

1576 Mr. Matthews. Sure.

1577 Mr. Carter. \$229 million to \$4 billion.

1578 And, of course, for those people who don't know, DIR
1579 fees are essentially clawback fees that go to the, the PBMs
1580 put on, placed on the pharmacies.

1581 You also mentioned that the amount of the DIR fees that
1582 the plan sponsors were recouping actually exceeded what they
1583 had proposed and what they had really had projected. Can you
1584 comment on or explain what that disparity might mean for cost
1585 sharing?

1586 Mr. Matthews. So, yes. What the short answer is that
1587 this means beneficiaries at the point of sale are paying a
1588 much greater amount in cost sharing than they should be
1589 relative to the effective transaction price between the
1590 manufacturer and the plan.

1591 Mr. Carter. Exactly. Exactly. But and I know that
1592 MedPAC has put out some different solution to the DIR fees,
1593 but the point is that you agree that DIR fees are a problem?

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1594 Mr. Matthews. Yes, sir, that is correct.

1595 Mr. Carter. Okay, good.

1596 Very quickly in what little time I have left, of course
1597 one of the things that we've been talking on this committee
1598 and in Energy and Commerce, and specifically on the O&I
1599 committee has been insulin pricing. And I just wanted you to
1600 comment very quickly that I understand there is a lot of
1601 variability in the different plans on how they cover insulin,
1602 but can you, can you explain how the Medicare plans cover
1603 insulin, particularly for those patients who are in the donut
1604 hole?

1605 Mr. Matthews. If I could get you to ask the question
1606 just slightly differently?

1607 Mr. Carter. Well, in other words, I know the different
1608 Medicare Part B plans cover it in different ways. But making
1609 it affordable, making it accessible is something we are very
1610 concerned with, particularly on this committee. How can we
1611 do that? How can those plans do that in a better way?

1612 Mr. Matthews. Again, our recommendation to restructure
1613 the Part D benefit would mitigate the incentives for plans to
1614 use these high-cost, high-rebate drugs. And insulin is one
1615 example of those kinds of things. And by better aligning the
1616 plans' incentives it would potentially reduce the influence

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1617 of DIR on the cost that the beneficiary faces.

1618 Mr. Carter. Right. Again I want to thank you for your
1619 work on transparency and accountability within the system,
1620 particularly with the third party, the pharmacy benefit
1621 managers, the middleman, that is what is going to help us.
1622 And, you know, transparency is the best disinfectant out
1623 there, and sunlight is, and that is why we need it so bad.

1624 So, thank you for your work on this, and I yield back.

1625 Ms. Eshoo. The gentleman yields back.

1626 I now would like to recognize the gentleman from North
1627 Carolina, George Butterfield. And happy birthday to you
1628 again.

1629 Mr. Butterfield. I have been multitasking today and I
1630 don't have any questions.

1631 Ms. Eshoo. You don't?

1632 Mr. Butterfield. If you can believe that.

1633 Ms. Eshoo. Isn't that something.

1634 Mr. Butterfield. Yes.

1635 Ms. Eshoo. Well, a lot of good ones have been asked, so
1636 stay tuned.

1637 All right. Well, with that we will move to the
1638 gentlewoman from Delaware, Ms. Blunt Rochester, for five
1639 minutes of questioning.

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1640 Ms. Blunt Rochester. Thank you, Madam Chairwoman. And
1641 I would also like to thank you, Dr. Matthews, I am trying to
1642 speak into the mike now I am cognizant of it.

1643 Today's hearing is an opportunity for the subcommittee
1644 to continue our bipartisan work on lowering prescription drug
1645 costs by turning our attention to how skyrocketing prices are
1646 impacting Medicare Part B and D. And it couldn't happen at a
1647 more important time. Prescription drug spending accounts for
1648 nearly one dollar out of every five spent on Medicare and,
1649 according to the Kaiser Family Foundation, was 19 percent of
1650 overall Medicare spending in 2016.

1651 The Office of the Actuary at CMS found that the national
1652 health expenditures will continue to increase by an annual
1653 average of 5.5 percent until 2027. These spending trends
1654 mean that it is not just the Federal Government that is
1655 paying more but Medicare beneficiaries. And in my state that
1656 means growing costs for the almost 200,000 Medicare
1657 beneficiaries.

1658 Dr. Matthews, I would like to discuss Part B's, Medicare
1659 Part B's low income subsidy which helps provide beneficiaries
1660 with limited incomes assistance with their Part D premiums
1661 and out-of-pocket expenses.

1662 In 2018, 12.5 million beneficiaries with incomes at or

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1663 below 100 percent of the federal poverty level received
1664 federal assistance. And in Delaware, 23 percent of
1665 beneficiaries received the low income subsidy. However,
1666 MedPAC has found that relative to other Part D enrollees, a
1667 higher proportion of LIS enrollees use brand name drugs.

1668 Can you explain why this is happening?

1669 Mr. Matthews. Okay. The dominant hypothesis that has
1670 guided our thinking here is that the low income beneficiary
1671 whose costs are heavily subsidized is not as sensitive to
1672 cost sharing or the price of the drugs that they take
1673 relative to a beneficiary who is paying, you know, the full
1674 co-insurance and their full out-of-pocket liability. And so,
1675 given the choice between a brand name drug and a generic,
1676 many Medicare patients who regard generics as not as good, a
1677 low income beneficiary who is facing zero or minimal cost
1678 sharing is going to opt for the brand name when it is
1679 available.

1680 Ms. Blunt Rochester. Right. Opt for the one that they
1681 rationally think is the better --

1682 Mr. Matthews. Yes.

1683 Ms. Blunt Rochester. -- product.

1684 Additionally, MedPAC found that in 2016, about 8 percent
1685 of Part D enrollees reached the out-of-pocket threshold. And

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1686 of that 8 percent of high cost enrollees, over 70 percent
1687 were LIS beneficiaries. And given that it is the Medicare
1688 program that pays the largest share of costs out of -- above
1689 the out-of-pocket threshold, I am concerned that plans may be
1690 structuring their benefits in ways that shift costs to
1691 Medicare for these, these enrollees in order to shield plans
1692 from risk.

1693 Does MedPAC share these concerns?

1694 Mr. Matthews. Our concerns are more with, are even
1695 larger than that, not limited just to the low income
1696 beneficiaries. But, again, given the growth in the cost-
1697 based reinsurance payments for all Part D enrollees, we
1698 believe that is an extremely pressing problem for the
1699 program. And while in the earlier phases of the Part D
1700 benefit LIS enrollees did reach the catastrophic phase at
1701 faster rates and in greater proportions, in recent years it
1702 is the non-LIS population who is now hitting that cap at much
1703 higher rates.

1704 Ms. Blunt Rochester. I know one of the things that you
1705 discussed before were the incentives, you know, to
1706 incentivize beneficiaries to pick a cheaper alternative. Can
1707 you talk about the options that you gave, are these evidence-
1708 based? Where did these ideas come from? How do you know

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1709 they will work? You had, you listed, like, zero copayments,
1710 you talked about nominal financial incentive. Can you talk
1711 about where you got that from and why you think it will work?

1712 Mr. Matthews. Yeah, with permission, I would like to be
1713 able to follow up.

1714 Ms. Blunt Rochester. Great.

1715 I appreciate MedPAC's thoughtful analysis on this issue
1716 and so many issues within the Medicare program. Low income
1717 Part D beneficiaries on tight incomes, there are many of
1718 them, and we must be doing all we can to ensure that they
1719 also have access to the medications that they need, while
1720 ensuring that there are not perverse incentives that keep
1721 drug prices high.

1722 I thank you and I yield back.

1723 Mr. Matthews. Thank you.

1724 Mr. Butterfield.[Presiding.] Thank you, Ms. Blunt
1725 Rochester.

1726 The gentlelady from California, Ms. Barragan, is
1727 recognized for five minutes.

1728 Ms. Barragan. Thank you.

1729 I want to follow up on the questioning from one of my
1730 colleagues on Medicare Part D negotiating. I know that you
1731 indicated that MedPAC has not taken a position on that. We

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1732 had a hearing a few weeks ago, we had the drug manufacturers
1733 come in and PBMs come in. I asked them if they were for or
1734 against a proposal to have Medicare negotiate. And they were
1735 against it. Not surprising to many, concerned about profits
1736 and so on and so forth.

1737 I am really glad to see in the committee that we are
1738 working on a bipartisan basis to bring down the price of
1739 prescription drugs. But I, having heard from my colleagues
1740 who sit on other committees for the VA, and everything I have
1741 read, it seems to me that -- and certainly hearing from you
1742 that you have no means to influence price -- it seems to me
1743 that if that were lifted, it would actually provide some
1744 leverage for us to bring down the cost of prescription drugs
1745 to the American people.

1746 Has MedPAC done any type of study on how much money the
1747 American people would save if Medicare had the ability to
1748 negotiate drug prices?

1749 Mr. Matthews. MedPAC has not done its own independent
1750 assessment of the viability of direct negotiation between the
1751 secretary and manufacturers.

1752 When others, such as our colleagues at CBO, have looked
1753 at this issue they have determined that without the secretary
1754 having very, very strong leverage, such as Medicare coverage

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1755 or Medicare payment, or other alternatives that have been
1756 proposed related to things outside of my purview such as
1757 patent changes, that the secretary is unlikely to achieve
1758 substantial savings through direct negotiation without being
1759 able to use those kinds of very strong negotiating tactics.

1760 Ms. Barragan. Can Medicare, rather can MedPAC do a
1761 study on this so that Congress has a report to look at and to
1762 look at these factors that you are discussing? Will MedPAC
1763 commit to doing something like that?

1764 Mr. Matthews. We could potentially look at some of the
1765 issues that would pertain to a direct negotiation scenario.
1766 So, you know, for example would this be across-the-board all
1767 drugs, all manufacturers? Does the agency have the resources
1768 to conduct these kinds of evaluations? What the evidence
1769 base is for the secretary's ability to negotiate a given
1770 price? We could look at those sorts of issues in a
1771 qualitative way.

1772 I don't know that we would have the capacity to or the
1773 desire to second guess our colleagues at CBO with respect to
1774 calculating potential savings.

1775 Ms. Barragan. Okay. Well, anything you could provide
1776 to Congress could be helpful, especially because this has
1777 been a bipartisan issue on a bipartisan basis, seems like a

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1778 way to move forward. So, given that you do, you work on a
1779 bipartisan basis --

1780 Mr. Matthews. Yes, ma'am.

1781 Ms. Barragan. -- I think any information will be
1782 helpful. Thank you for that.

1783 I want to chat quickly about the issue of minority
1784 health disparities. Across this country, you know, people
1785 based on race are treated differently in our health care
1786 system, we have different health impacts and outcomes. For
1787 example, HIV diagnosis rate among Hispanic men is more than
1788 three times the HIV diagnosis rate among non-Hispanic white
1789 men. African Americans are also more than twice as likely as
1790 whites to be diagnosed with and die from blood cancer and
1791 multiple melanoma.

1792 My district is majority minority. It is about 80
1793 percent Latino/African American. I have the highest rate of
1794 diabetes than any other congressional district in the State
1795 of California. And we touched a little bit upon low income
1796 communities and how Medicare actually has low income
1797 subsidies for patients. But the annual income is pretty low.
1798 I think it is about \$18,735. In California it is easy to
1799 miss that a little bit. And they are not qualified.

1800 And my concern is the connection between costs and the

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1801 continuing impacts and effects on minority health
1802 disparities. Has MedPAC or CMS done any type of study to
1803 determine whether minority communities have similar outcomes
1804 from the Medicare Part D program as non-minority communities?

1805 Mr. Matthews. Not to the best of my knowledge.

1806 Ms. Barragan. Is that something you could do? I know
1807 you mentioned you do a lot of, you look at tradeoff and
1808 balances. But, you know, when we are talking about
1809 communities of color, racial health disparities is an issue.
1810 There shouldn't be really a tradeoff or balance with their
1811 health.

1812 Mr. Matthews. Understood. What is outlined here is a
1813 fairly broad endeavor though. And with, again with all due
1814 respect, if you could grant me the leeway to go back and talk
1815 to my staff about what we can and can do with -- or can and
1816 can't do with the resources that we have available to us we
1817 would certainly be willing to take a look at this.

1818 Ms. Barragan. Great. Thank you. I yield back.

1819 Mr. Butterfield. Thank you. The gentleman from Montana
1820 is recognized for five minutes.

1821 Mr. Gianforte. Thank you, Mr. Chairman.

1822 Okay, thank you. Drug prices in the Medicare program
1823 keep rising and it is making it tougher for seniors in

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1824 Montana to afford their prescriptions. Dr. Matthews, last
1825 August several members of the committee wrote to MedPAC and
1826 asked the commission to examine the trend of hospital
1827 consolidation and how much consolidation increases the costs
1828 to Medicare, the Medicare program and beneficiaries,
1829 including the costs of prescription drugs. So, I want to
1830 focus on this issue today.

1831 Since we are discussing prescription drug prices, can
1832 you please update us on MedPAC's findings, specifically the
1833 impact of hospital consolidation and acquisition of physician
1834 practices on the cost of prescription drugs to the Medicare
1835 program and seniors' out-of-pocket expenses?

1836 Mr. Matthews. Yes, sir. So, I don't have any update
1837 with respect to work we have currently underway in response
1838 to the most recent request. But as you know, a couple of
1839 years back we did a chapter in a June report looking at the
1840 effects of consolidation on Medicare spending, and looked at
1841 the impacts of both vertical integration where different
1842 levels of the health care system form single entities or
1843 horizontal integration such as where all cardiologists
1844 integrate under a single organization.

1845 And so both of those types of consolidation do have the
1846 potential to increase spending for the Medicare program.

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1847 Mr. Gianforte. So, that request that was made, the work
1848 is still ongoing?

1849 Mr. Matthews. Yes, sir, that is correct.

1850 Mr. Gianforte. Okay.

1851 Mr. Matthews. And we anticipate starting to roll that
1852 out in the fall of this year.

1853 Mr. Gianforte. Okay, thank you.

1854 How do significant payment differences for identical
1855 medical services performed in Medicare at hospital outpatient
1856 departments versus independent physician practices impact
1857 seniors' out-of-pocket costs for Part B drugs?

1858 Mr. Matthews. It has the potential to substantially
1859 impact their out-of-pocket costs. But I use the word
1860 "potential" deliberately. And the reason I do that is
1861 because most Medicare beneficiaries in fee-for-service
1862 Medicare do have some secondary coverage. They are dual-
1863 eligibles, they have employer-sponsored wrap-around
1864 insurance, or they purchase Medigap.

1865 And so, to some extent they are insulated from the
1866 direct effects of these payment differentials across
1867 settings. But nonetheless, all Medicare beneficiaries are
1868 experiencing these effects through higher Part D premiums.
1869 And those beneficiaries who elect to purchase Medigap are

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1870 paying higher Medigap premiums as a result.

1871 Mr. Gianforte. Okay. And has MedPAC made any
1872 recommendations to address this differential?

1873 Mr. Matthews. We have. It's been several years now
1874 where we identified a set of services meeting certain
1875 criteria: if they are majority provided in physicians'
1876 offices, they are majority not associated with emergency
1877 care, and identified services that are appropriate candidates
1878 for a Medicare site mutual payment policy.

1879 Mr. Gianforte. Okay. And if Congress required Medicare
1880 to pay the same amount for services regardless of where they
1881 are performed, would seniors' out-of-pocket prescription drug
1882 costs decrease? And what effect would it have on Medicare
1883 overall costs?

1884 Mr. Matthews. Off the top of my head I could not
1885 venture an answer with respect to the effects on their drug
1886 costs. It is something we could think about.

1887 Mr. Gianforte. Okay. So that is something you could
1888 look into additionally. Because this is the concern we hear
1889 back home is --

1890 Mr. Matthews. Understood.

1891 Mr. Gianforte. -- the overall cost, and prescription
1892 drugs area big piece of that. So, we very much appreciate

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1893 your, your help to --

1894 Mr. Matthews. Yes, sir.

1895 Mr. Gianforte. -- chart a path for us.

1896 Mr. Matthews. Yes, sir.

1897 Mr. Gianforte. And I thank you for your testimony

1898 today. With that, Mr. Chairman, I yield back.

1899 Mr. Butterfield. Thank you.

1900 The gentlelady from Illinois, Ms. Kelly, is recognized

1901 for five minutes.

1902 Ms. Kelly. Thank you, Mr. Chair. Dr. Matthews, thank

1903 you for being here, and thank you for your testimony and

1904 sharing MedPAC's work on these important issues.

1905 As you point out in your testimony, there are a handful

1906 of expensive drugs driving spending in the Part D program,

1907 with consumers responsible for significant out-of-pocket

1908 costs. The top ten highest expenditure drugs accounted for

1909 about 43 percent of Part D drug spending in 2017. And all of

1910 these project -- products, excuse me, are biologics. Some of

1911 these drugs have competitors and others do not.

1912 I would like to learn more about the impact a biosimilar

1913 entry into the market had to date on the price of the

1914 originator biologics driving costs in Part D. You have

1915 shared what drugs a program is spending the most money on and

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1916 the conditions these drugs treat. But how many of the top
1917 ten highest expenditure drugs in Part D face competition from
1918 a biosimilar?

1919 Mr. Matthews. As I recall, there are two products out
1920 of that top ten list that have biosimilar competitors. And
1921 the biosimilars have not had a substantial impact on the
1922 price that Medicare pays for the originator biologics. In
1923 part, this probably reflects the way Medicare pays for the
1924 biosimilars relative to the innovator biologic.

1925 The innovator biologic gets its own payment code and its
1926 own 6 percent add-on. The biosimilar gets its own payment
1927 code, even if it is at a lower price, but it gets the 6
1928 percent add-on that is associated with the innovator product.

1929 So, from the prescriber's perspective, the physician who
1930 administers the drug, it is a neutral decision whether to use
1931 the innovator product or the biosimilar.

1932 MedPAC has recommended that instead of those two
1933 products having unique codes, that you would potentially
1934 influence price to a much greater extent by combining them
1935 and having the program pay the average of the sales prices of
1936 those two products.

1937 Ms. Kelly. Okay. And I understand what you are saying
1938 that there has only been a modest impact on prices --

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1939 Mr. Matthews. That is right.

1940 Ms. Kelly. -- to date and your recommendations for
1941 what we can do about it.

1942 Can you discuss how original biologics and biosimilars
1943 are currently grouped, and what the commission has
1944 recommended to result in price reduction there?

1945 Mr. Matthews. Yeah. Again, under current payment
1946 policy the innovator biologics and each biosimilar get their
1947 own payment code. And, again, in an attempt to make the
1948 decision financially neutral from the prescriber's
1949 perspective, the 6 percent add-on for any of those products
1950 if the add-on associated with the originator product.

1951 And so, again, our recommendation would be that instead
1952 of having, let's say, a \$1,000 drug that gets a \$60 add-on,
1953 and then a \$100 drug or biologic that gets a \$60 add-on, that
1954 instead we would average the \$1,000 bio -- referenced
1955 biologic and the \$100 biosimilar and have Medicare pay that
1956 rate, which would give providers a much greater incentive to
1957 use the biosimilar and potentially start to move the price of
1958 the referenced biologic down in a way that we have not yet
1959 seen.

1960 Ms. Kelly. Is there, as we have been sitting here, is
1961 there anything that we haven't asked you that you want to

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1962 tell us?

1963 Mr. Matthews. No, ma'am. I do not want to venture any
1964 of my own questions here, so.

1965 Ms. Kelly. Well, thank you. A major goal of this
1966 committee in our drug pricing work to date has been to remove
1967 the barriers to generic competition and stop anticompetitive
1968 practices. It is important for us to continue to examine
1969 policies that would support competition in all markets to
1970 lower costs facing consumers. Everyone should have access,
1971 as you know, to the care and medication they need.

1972 And thank you, and I yield back.

1973 Ms. Eshoo.[Presiding.] The gentlewoman yields back.

1974 And I now would like to recognize the gentleman from
1975 Vermont, Mr. Welch.

1976 Mr. Welch. Thank you.

1977 Ms. Eshoo. Happy birthday to you.

1978 Mr. Welch. Well, thank you.

1979 Ms. Eshoo. Thank God you were born.

1980 Mr. Welch. Some people agree with that. Thank you.

1981 Dr. Matthews, really good testimony, so thank you very
1982 much, and really good work.

1983 It is really frightening, the cost of prescription
1984 drugs, and it is really frightening how the market power that

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1985 is out there is so aggressively used no matter how much pain
1986 is inflicted on folks. You know, I was here when Mr. Bucshon
1987 was raising some questions about a formulary. And a lot of
1988 people have that question: is that going to impede access. I
1989 was talking to Senator Grassley. He had that concern.

1990 And one of the approaches that we took in Vermont,
1991 because here is the dilemma as I understand it, if you have a
1992 strict formulary you tend to get more savings but less
1993 patient choice. But if you have a wide open formulary with
1994 patient choice you get no savings. So how do you, how do you
1995 deal with that?

1996 And what we did in Vermont is we basically made it
1997 pretty easy for a doctor to override what the formulary was
1998 because it might be that Mr. Bucshon, or Dr. Bucshon and I
1999 have the same condition but the medication that works for him
2000 is different than the one that works for me. I mean, is that
2001 a possible way to try to thread the needle here where we
2002 maintain patient choice but get the benefit where in the vast
2003 majority of time medication A is probably going to be good
2004 for Dr. Bucshon as well as good for me? Is that a possible
2005 path forward on this?

2006 Mr. Matthews. Potentially. And as I said in my
2007 comments earlier, we do think that there should be very

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2008 robust exceptions and appeals avenues available for Part D
2009 enrollees and their physicians. But at the same time, you
2010 know, we are trying to balance the plan's ability to leverage
2011 price from the manufacturer. And --

2012 Mr. Welch. Right. And I agree with that. But the fact
2013 is that there is going to be a lot of resistance if there is
2014 an apprehension that a patient can't get the medication he or
2015 she needs. So it has to be simple.

2016 But the incentives that are built into the system right
2017 now that you outlined are totally in favor of higher prices.
2018 You know, if you can get somebody into the specialty drug
2019 program, then that is a real burden on the taxpayer. The
2020 patient has no clue really, because we rely on what the
2021 doctor tells us.

2022 So, I would just urge us to try to look for some way
2023 where we address this patient choice issue because I know a
2024 lot of my colleagues have that concern. I have that concern.

2025 Mr. Matthews. Sure.

2026 Mr. Welch. But we've got to get the benefit of that
2027 formulary.

2028 Now, the other thing is we are the only government that
2029 I am aware of that really doesn't play an active role in
2030 trying to provide some pricing protection to benefit our

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2031 taxpayers and consumers. And you gave the shocking
2032 statistics about the specialty drugs and how awhile ago what
2033 was it, 33,000 people went immediately into --

2034 Mr. Matthews. Yes, sir. That was in 2010. The number
2035 in 2017 is now 370,000.

2036 Mr. Welch. Yeah. So it is one prescription --

2037 Mr. Matthews. Sure.

2038 Mr. Welch. -- gets them into that high pay, high
2039 taxpayer pay situation.

2040 Now, would you be supportive of legislation which would
2041 have price negotiation available as a tool for MedPAC and, in
2042 the event that failed, have arbitration to come up with a
2043 price that is "fair"?

2044 Mr. Matthews. The commission has not weighed in on the
2045 broader question of direct negotiation. Our standing
2046 recommendation would include binding arbitration as part of
2047 our DVP proposal, which we recommended in 2017. And we are
2048 currently exploring whether or not binding arbitration could
2049 have a potentially greater role in the Medicare program. But
2050 we have not --

2051 Mr. Welch. You could have the binding arbitration in
2052 some of the highest cost specialty drugs.

2053 Mr. Matthews. Yes, sir. That is correct.

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2054 Mr. Welch. And that would have a huge impact on the
2055 cost of the overall to the taxpayer and to the plans.
2056 Correct?

2057 Mr. Matthews. Yes, sir, that is correct.

2058 Mr. Welch. Yeah, I mean, you know, again I am going to
2059 focus on Dr. Bucshon here a minute because I know what a
2060 dedicated physician he has been. We just have this dilemma:
2061 you just can't have it all. Okay. You just can't have it
2062 all. And the cost side on health care is where all the pain
2063 is. And if we just have these costs go out of control,
2064 continue to go out of control, that cuts off access.

2065 So there has got to be some tradeoffs is my view here.
2066 Would you agree with that, Dr. Matthews?

2067 Mr. Matthews. Yes, sir. It is all about tradeoffs.

2068 Mr. Welch. And there is some argument that is always
2069 made by the pharma companies that if there is some pushback
2070 on their pricing power, that somehow means they are not going
2071 to innovate. I find that to be bogus because they are
2072 spending more on advertising than they are on research.
2073 There is an enormous amount of research funded by taxpayers
2074 through the National Institute of Health. There is an
2075 enormous amount of research funded by taxpayers through the
2076 research and development tax credit.

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2077 Do you see that if we have reasonable interaction by the
2078 government to negotiate prices or to have an arbitration
2079 system with neutral parties that that would have -- that
2080 would impede innovation?

2081 Mr. Matthews. As we have contemplated binding
2082 arbitration, we do not believe that it would stifle R&D for
2083 true innovative new products where the manufacturer would
2084 have an opportunity to come before a neutral arbitrator, or
2085 arbitrator, I never know which the right word is, but present
2086 evidence in terms of R&D costs, in terms of foregone
2087 additional spending for the use of their product. And --

2088 Mr. Welch. And you would get some transparency out
2089 there?

2090 Mr. Matthews. Yes.

2091 Mr. Welch. Again, Madam Chair, I think that is why this
2092 hearing is so important. I mean, this is not a he said/she
2093 said deal. We are all losing on this thing.

2094 So, I appreciate that testimony and the good work you
2095 have done over the years. And, hopefully, this committee can
2096 start moving forward to help bring these prices down.

2097 I yield back.

2098 Ms. Eshoo. I thank the gentleman, and he yields back.

2099 And I also want to acknowledge, and I think I was

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2100 leaving the hearing room to run downstairs to the other
2101 hearing, and I did not get to wish our colleague
2102 Congresswoman Robin Kelly a happy, blessed, wonderful
2103 birthday, because you are all three.

2104 With that, I am pleased to recognize the gentleman from
2105 Florida, Mr. Soto, for five minutes of questioning.

2106 Mr. Soto. Thank you, Madam Chairwoman.

2107 We saw in our committee analysis we are paying 104.3
2108 percent average sales price to providers, down from 1.6
2109 percent because of sequester. And we all realize this is an
2110 incentive to purchase drugs at a higher average sales price
2111 and receive a higher reimbursement.

2112 We saw CMS roll out a plan recently last year to have
2113 pharmaceutical vendors purchase and sell directly to
2114 patients, circumventing this provider cost escalation
2115 incentive, providing flat fees to providers and time
2116 reimbursements to international pricing.

2117 For my constituents at home will this do the job or are
2118 there other things we should be doing going along with what
2119 Congressman Ruiz talked about potential arbitration or other
2120 ideas? What is MedPAC advising?

2121 Mr. Matthews. Okay.

2122 Mr. Soto. Just broad points.

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2123 Mr. Matthews. Yes, sir. So, I am not familiar with the
2124 proposal to have manufacturers sell directly to patients, if
2125 I understood your question correctly. So, again I would ask
2126 for the dispensation to come back to you on that point.

2127 With --

2128 Mr. Soto. So, basically it is saying allow private
2129 sector pharmaceutical vendors to buy and bill Medicare for
2130 drugs and supply those drugs to providers, rather than the
2131 providers doing so directly?

2132 Mr. Matthews. Yes. So, this is part of the IPI
2133 proposal that the Administration has put forward. And again,
2134 while we do support the Administration's desire to reduce the
2135 prices that Medicare beneficiaries pay for prescription
2136 drugs, particularly in light of prices that citizens of other
2137 countries are paying, but at the same time we think there are
2138 certain logistical and implementation issues with respect to
2139 the Administration's proposal that would make it less likely
2140 to succeed than --

2141 Mr. Soto. What are those specifically?

2142 Mr. Matthews. So, again, under the Administration's
2143 proposal, Medicare would set a price that it will pay the
2144 vendor based on the international reference price. And it is
2145 incumbent upon the vendor to try and obtain that price from

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2146 manufacturers.

2147 But the proposal, if I recall correctly, does not give
2148 the vendor much by way of negotiating tools in order to
2149 extract that price.

2150 Mr. Soto. So, that is where this arbitration idea that
2151 is being mulled around in this committee --

2152 Mr. Matthews. Yes, sir.

2153 Mr. Soto. -- is so critical because that could create
2154 a more arms-length transaction to get the most efficient
2155 price. Is that correct?

2156 Mr. Matthews. That is correct.

2157 Mr. Soto. I wanted to move into some other ideas
2158 pitched by HHS, particularly step therapy and higher
2159 authorization. Certainly with lesser conditions these can be
2160 cost saving. But I worry when you apply it to cancer and
2161 other potentially fatal conditions that this step therapy and
2162 prior authorization, particularly step therapy, leads to time
2163 running out and people dying, literally, of cancer because
2164 they are given less effective drugs earlier on in the step
2165 therapy. And that we end with a death that could have been
2166 prevented.

2167 Do you think there should be a carve-out for cancer and
2168 other fatal conditions with regard to step therapy?

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2169 Mr. Matthews. The commission has not contemplated the
2170 need for a carve-out or exceptions based on medical condition
2171 or a patient's diagnosis. But we have recognized, again, the
2172 need for a very robust and very expeditious exceptions and
2173 appeals process as part of the use of utilization management
2174 tools on the part of plans.

2175 Mr. Soto. And going into another issue that we continue
2176 to see is in the private market drug prices going three,
2177 four, ten times the amount of increases. What role should we
2178 play in stopping this from happening? And how does that
2179 affect Medicare when we see a drug that has been around for
2180 20 years that has a 10, 10 to 20 percent -- 10 to 20 times
2181 increase? What are you advising us to do?

2182 Mr. Matthews. Right. So that is actually an insightful
2183 distinction that if I could take a minute.

2184 Mr. Soto. Yes.

2185 Mr. Matthews. So, one, you know, we have seen the entry
2186 of truly revolutionary blockbuster products on the market
2187 that cure things like Hep C. So, the Sovaldis, the Harvonis
2188 where the benefits of the medication potentially warrant the
2189 prices that the manufacturer is charging.

2190 But we also see, and the commission is extremely
2191 concerned about instances that you just alluded to where you

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2192 have products that have been on the market for decades where
2193 there is no real active research and development to
2194 increasing the efficacy of these products. And yet, the
2195 prices continue to increase year over year.

2196 And while there may be costs and R&D going on beyond,
2197 behind the scenes that people like me don't see, we still
2198 think that those kinds of cost increases are not warranted,
2199 given our responsibility to a public program like Medicare.
2200 And so, we have recommended an inflation rebate that would
2201 check the ability of manufacturers to increase their prices
2202 on a year over year basis in excess of some defined rate of
2203 inflation.

2204 Mr. Soto. Thank you. I yield back.

2205 Ms. Eshoo. The gentleman yields back.

2206 It is a pleasure to recognize the gentleman from
2207 Maryland, Mr. Sarbanes, for five minutes of questioning.

2208 Mr. Sarbanes. Thank you.

2209 Thank you, Dr. Matthews, your testimony today has been
2210 excellent. You are definitely going to get called back by
2211 many, many committees in the future.

2212 Mr. Matthews. I am sorry to hear that.

2213 Mr. Sarbanes. You did a great job.

2214 I wanted to pick up actually right where Congressman

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2215 Soto left off because you mentioned this inflation rebate as
2216 a way of trying to get to some of these significant price --
2217 Mr. Matthews. Yes, sir.

2218 Mr. Sarbanes. -- increases. And it seems to me that,
2219 arguably, is the other side of a coin where you could think
2220 about setting, or we could think about setting upper limits
2221 on the prices of some of these drugs. It is just a different
2222 way of accomplishing the same thing.

2223 Would you agree with those as sort of two sides of the
2224 same coin potentially?

2225 Mr. Matthews. Potentially, yes.

2226 Mr. Sarbanes. Yeah. And I note that there is a number
2227 of states which have begun to explore regulating prescription
2228 drug pricing within their own jurisdictions. Maryland
2229 recently created, the Maryland General Assembly passed
2230 legislation.

2231 I think it is the first state to actually get this
2232 passed, it is now subject to the governor's signature, that
2233 would create a prescription drug affordability board. And
2234 the board would have the authority to review drug cost data
2235 that manufacturers submitted, and then they could set an
2236 upper payment limit on those prescription drugs. And I think
2237 there are six or seven other states that are exploring the

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2238 same sort of approach.

2239 We have talked about a number of strategies to address
2240 drug pricing. And we have also talked about how you have
2241 made recommendations on how Medicare can try to manage the
2242 situation downstream a little bit, if you view the original
2243 pricing that the manufacturers are setting as kind of the
2244 ultimate upstream point in the continuum.

2245 There are all these efforts downstream, bringing the
2246 plans in, trying to incentivize them more to manage costs so
2247 the program isn't taking as big a hit, et cetera. But if we
2248 go to the source, which is the pricing that the manufacturers
2249 are setting, there is increasingly I think a sense in this
2250 Congress on both side of the aisle that we have to take some
2251 pretty dramatic steps to control the costs and the price
2252 setting at that end.

2253 But what is your view of this concept of regulating or
2254 setting upper limits on the prices of these various
2255 categories of prescription drugs?

2256 Mr. Matthews. Okay. So, so again, the commission
2257 hasn't taken a position with respect to setting a specific
2258 cap on a price. Although I do see the analogy between
2259 setting a hard cap on a price versus setting a cap on the
2260 rate that a price can increase over time.

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2261 I am also not personally familiar with the details of
2262 the state efforts that you have just described, but it is
2263 something we can start to look at and see if there is any
2264 model there.

2265 But, with respect to our inflation rebate, it is guided
2266 by the notion that for drugs that have been on the market for
2267 some period of time where they are established therapies
2268 whose indications are known, and their effects are known,
2269 that to some extent these are commodities, and the
2270 expectation of commodity prices is that they should go down
2271 over time.

2272 When you look at things like computers or wide screen
2273 T.V.'s you are getting better and better technology with each
2274 passing year at lower prices. And the question is why these
2275 trends work in reverse for prescription drugs, especially
2276 these therapies that are, again, long-extant on the market.

2277 And so we think that at a minimum, setting a limit that
2278 those prices can increase year over year is a step in
2279 moderating these effects that we have seen that have very
2280 detrimental effects on the Medicare program.

2281 Mr. Sarbanes. Well, I think we need to put every option
2282 on the table. The rebate is, I would say, a step in the
2283 right direction, an inflation rebate. But we need to be

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2284 looking at negotiating power on the part of the Medicare
2285 program. Many have talked to that. The arbitration approach
2286 is another. Maybe some form of, like, public auction around
2287 the pricing of these drugs. And even the notion of
2288 regulating these, these drugs as a utility.

2289 I mean, if you look at there is a lot of, there is a lot
2290 of analogies you can draw between the public good aspect of
2291 how drugs are delivered to pretty much every American and the
2292 way electricity is delivered, or water is delivered, or, you
2293 know, health care premiums are set. So I think there is
2294 going to be a lot more activism on our part here in Congress
2295 with respect to the pricing of drugs.

2296 Thank you for your testimony today. This was extremely
2297 helpful. I yield back.

2298 Mr. Matthews. Thank you. Thank you.

2299 Ms. Eshoo. The gentleman yields back.

2300 I am going to recognize myself for an additional five
2301 minutes, and also the ranking member as well for a couple of
2302 follow-up questions.

2303 First, Dr. Matthews, again thank you. I think it is
2304 very clear that the committee on a bipartisan basis clearly
2305 has more than an interest in addressing drug prices.

2306 I would encourage MedPAC to go back and continue to make

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2307 recommendations on how to protect patient access. I know
2308 that in the original legislation that created MedPAC, when
2309 Medicare Part D was created so was MedPAC. But to leave out
2310 patients in this, I mean, this is not just a program where
2311 numbers are shifted around. The numbers apply to people, to
2312 human beings. And I don't see how that element can be left
2313 out of your deliberations.

2314 And as we work to reduce costs, that too has an effect
2315 on, as we have heard from questions and your responses, that
2316 too has an effect on patients.

2317 Now, this whole issue of step therapy, I don't see how
2318 MedPAC can just stick with what seems to me a conversation
2319 about tools and the kit, et cetera, et cetera, when people
2320 have actually died because they don't have access to what
2321 they need. We can't ignore that, nor can MedPAC. So, while
2322 this step therapy has been created so that, as you describe
2323 it more tools in the kit to reduce and control pricing and
2324 whatever, when people are dying because they can't get what
2325 they need and they are pushed back to step one.

2326 Step one the doctor knows is not going to work, step two
2327 the doctor knows is not going to work, but you never get to
2328 three because you haven't lived long enough, that doesn't
2329 make sense. It just doesn't. I mean, it is not defensible

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2330 in my view and I think in other members' views as well.

2331 I don't know who supports this thing. It is from the
2332 both side of the aisle you have heard about it. We have
2333 heard from our constituents. They don't identify themselves
2334 to us as Republicans or Democrats, they are our constituents.

2335 And the issue that you have raised that since the
2336 program was founded, was put together, that there has been a
2337 20 percent increase in D, if I heard you correctly, a 20
2338 percent increase on an annual basis relative to drug pricing
2339 is, to say it is a jaw-dropper doesn't begin to describe it

2340 And so I think we have our work cut out for us, but I
2341 think you do as well. And I think that MedPAC needs to step
2342 its game up, so to speak, in these, in these areas. And that
2343 you do it in a timely fashion so that you can make
2344 recommendations and some of these changes be recommended in
2345 these key areas.

2346 With that, I would like to recognize Mr. Bucshon and
2347 thank him for his support of an additional five minutes for
2348 myself and for himself as well. Thank you again.

2349 Mr. Bucshon. Thank you, Madam Chairwoman.

2350 I will make a few comments about the step therapy and
2351 prior authorization. I mean, I have been a physician for
2352 years, for many years, and this has been a concept that has

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2353 waxed and waned for the 30 years or so that I have been in
2354 medicine. And, you know, it is a concept that waxes and
2355 wanes because at the end of the day I would argue it
2356 ultimately doesn't save anybody any money because the delay -
2357 - it has a potential to delay therapy.

2358 And then as a cardiovascular surgeon I saw people in
2359 tertiary care situations in their lives, and I just, I have
2360 always had concerns about that. And I don't know if anyone
2361 has, has looked at the long term implications of that. And
2362 it may not be -- it is probably out of the scope of what you
2363 look at.

2364 Mr. Matthews. Yes, sir.

2365 Mr. Bucshon. But looking at delay in therapy, potential
2366 delay in therapy -- and, again, my argument that physicians
2367 generally will make the decision to treat their patients
2368 based on what they think is the best individual therapy for
2369 that patient. And do consider cost. Don't get me wrong. As
2370 I mentioned, I considered cost if there was equivalent
2371 therapy.

2372 The one thing I -- on the prior authorization, a number
2373 of years ago, maybe 10 or 15 years ago, there was one of the
2374 major private sector insurance companies that decided to drop
2375 their prior authorization program. Do you recall that at

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2376 all?

2377 Mr. Matthews. I do not. I am sorry.

2378 Mr. Bucshon. It might have been UnitedHealthcare. I
2379 can't recall. And don't quote me on that, but I just -- and
2380 then it has been, I think it has been reinstituted. But the
2381 reasoning behind that, I remember when that happened, was is
2382 because they found that whoever this was, and I am not saying
2383 it was them, is that at the end of the day it didn't save
2384 them anything because they were authorizing about 98 or 99
2385 percent and the administrative costs to deny the 1 or 1.5
2386 percent didn't outweigh the savings.

2387 Have you heard of that type of concept?

2388 Mr. Matthews. I have heard similar anecdotes. Again, I
2389 can't attribute them to a specific --

2390 Mr. Bucshon. Right.

2391 Mr. Matthews. -- instance. But yes.

2392 Mr. Bucshon. Yeah. And I would argue that that is
2393 probably the case. The administrative costs if you are going
2394 to, you know, if you are going to deny 10 percent or
2395 something I, I get that. I would say I would have an ethical
2396 problem with that. But if you were, then it might save you
2397 money. I don't know what the finances are on that.

2398 But there is a perception that it saves money, and I am

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2399 not sure that that is actually true.

2400 So I want to comment, that is my comments on those two
2401 things.

2402 Do you know if CBO has ever done studies on out-of-
2403 pocket cost caps? Like, say, if there was a cap set at a
2404 certain level what the, what the CBO score would be? There
2405 will be a score, right, because there will be a potential
2406 number of people that would go over, that would normally be
2407 over that level, whatever that cap is.

2408 Mr. Matthews. I believe that is correct, yes.

2409 Mr. Bucshon. And is that something that you think would
2410 be interesting to know for your purposes?

2411 Mr. Matthews. This would be for?

2412 Mr. Bucshon. For Medicare Part D. Like an out-of-
2413 pocket cost cap; right?

2414 Mr. Matthews. Yes. And this is something that MedPAC
2415 has recommended as part of our package of Part D
2416 recommendations.

2417 Mr. Bucshon. Right. The question would be is what
2418 level that the out-of-pocket costs are capped at.

2419 Mr. Matthews. That is correct.

2420 Mr. Bucshon. So the question would be is a CBO score on
2421 that at differing levels might be interesting information to

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2422 know. Would you agree or disagree with that? Or have they
2423 done it?

2424 Mr. Matthews. I am not aware that they have done this.
2425 But I don't disagree that it would be an interesting thing to
2426 know the effects at different level.

2427 Mr. Bucshon. Because if you were going, if Congress was
2428 going to say, okay, we are going to set an out-of-pocket cost
2429 cap at X dollars, right, the first thing we would do is get a
2430 CBO score.

2431 Mr. Matthews. Right.

2432 Mr. Bucshon. And see, well, what is that going to, what
2433 is that going to cost; right? Because there will be a cost
2434 if you set it, if you set it low enough there would be a
2435 cost.

2436 Mr. Matthews. Right.

2437 Mr. Bucshon. And so, maybe preemptively having a
2438 multitude of different cost levels known to Congress before
2439 we try to make some of these decisions might -- could be
2440 helpful. Would you think that would be the case?

2441 Mr. Matthews. Without committing my colleagues --

2442 Mr. Bucshon. I understand. I am not asking --

2443 Mr. Matthews. -- to doing this work.

2444 Mr. Bucshon. -- you for any commitment at all. Right.

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2445 Mr. Matthews. That is correct, yes.

2446 Mr. Bucshon. Yeah. I think that might very well be
2447 helpful.

2448 With that, Madam Chairwoman, I yield back.

2449 Ms. Eshoo. The gentleman yields back.

2450 Again I would like to thank you, Dr. Matthews, for your
2451 participation. And I hope that you didn't need to take any
2452 pain medication to come here today or anything else due to
2453 your testimony. But a first time out I think that we would
2454 all say that you, that you presented your case very well.

2455 I want to remind members that pursuant to committee
2456 rules they have ten business days to submit additional
2457 questions for the record to be answered by the witness who
2458 has appeared. We would appreciate your timely response to
2459 those, Dr. Matthews.

2460 And I, as I said, we really appreciate prompt responses
2461 to the question that you may receive.

2462 So, at this time, the subcommittee is adjourned.

2463 [Whereupon, at 12:43 p.m., the subcommittee was
2464 adjourned.]